

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(1) INTRODUCTION/1. The scope of control.

MEDICINAL PRODUCTS AND DRUGS (

1. CONTROL OF MEDICINAL PRODUCTS

(1) INTRODUCTION

1. The scope of control.

The Medicines Act 1968 provides a framework for the regulation and control of dealings with medicinal products¹. In general, the manufacture, assembly, sale, supply, import or export of a medicinal product in the course of a business is prohibited except under licence². There are a number of exemptions from these provisions in favour of doctors, dentists, veterinary surgeons and practitioners, pharmacists, nurses and midwives³. The ministers⁴ act as the licensing authority, and the Act provides for a scheme for the grant, refusal or renewal of licences⁵. The sale or supply of a medicinal product for the purposes of medicinal tests on animals is also regulated and is, in general, prohibited except when licensed by a certificate granted by the licensing authority⁶.

Part III of the Medicines Act 1968⁷ makes further arrangements for regulating the sale or supply of medicinal products. It provides for the establishment of a general sale list of medicinal products which can safely be sold without the supervision of a pharmacist⁸, and restricts the retail sale of medicinal products not on a general sale list to transactions carried out at registered pharmacies under such supervision⁹, although there are a number of exemptions from these requirements¹⁰. There is special provision for regulating the sale of medicinal products from automatic machines¹¹. Provision is also made for the establishment of a list of medicinal products which may only be sold or supplied by retail in accordance with a prescription given by an appropriate practitioner¹².

Contravention of the provisions of the Act or of any regulations made under it is, in general, a criminal offence¹³.

There is also significant control of medicinal products by way of European Union legislation¹⁴, and regulations have been made under the European Communities Act 1972 implementing this legislation in respect of marketing authorisations for medicines for human use¹⁵ and veterinary medicinal products¹⁶; clinical trials¹⁷; homoeopathic medicinal products for human use¹⁸ and veterinary use¹⁹; blood safety and quality²⁰; and medical devices²¹.

1 For the meaning of 'medicinal product' see PARA 7 post. The code is intended to be self-contained, and medicinal products are excluded, eg, from the consumer safety provisions of the Consumer Protection Act 1987 Pt II (ss 10-19) (as amended): see ss 11(7)(d), 19(1) (defining 'consumer goods' so as not to include medicinal products or other substances or articles in respect of which a product licence is in force under the Medicines Act 1968: see PARA 44 et seq post). As to consumer safety generally see SALE OF GOODS AND SUPPLY OF SERVICES vol 41 (2005 Reissue) PARA 528 et seq.

2 See PARA 42 et seq post. As to the postponement of the provisions relating to export see PARA 12 post.

3 See PARA 49 et seq post.

4 For the meaning of 'the ministers' see PARA 3 note 3 post.

5 See PARA 43 et seq post.

6 See PARA 126 et seq post.

7 le the Medicines Act 1968 Pt III (ss 51-68) (as amended): see PARA 133 et seq post.

8 See PARA 133 post.

9 See PARA 134 post.

10 See PARAS 137-139 post.

11 See PARA 136 post.

12 See PARAS 140-142 post.

13 See PARA 176 et seq post.

14 As to special provisions relating to the patenting of medicinal products see PATENTS AND REGISTERED DESIGNS vol 79 (2008) PARA 341 et seq. As to the provisions relating to the imposition of customs tariffs see CUSTOMS AND EXCISE vol 12(2) (2007 Reissue) PARA 2 et seq. As to provisions relating to the use of medicinal products in animal feeding stuffs see AGRICULTURAL PRODUCTION AND MARKETING vol 1 (2008) PARA 996 et seq.

15 See the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144; and PARA 18 et seq post. The consumer safety provisions of the Consumer Protection Act 1987 Pt II (as amended) (see note 1 supra) do not apply to medicinal products in respect of which a United Kingdom marketing authorisation or a Community marketing authorisation is for the time being in force: see the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 9(13). As to United Kingdom marketing authorisations and Community marketing authorisations see PARAS 19-20 post.

16 See the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142 (as amended); and PARA 34 et seq post.

17 See the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031 (as amended); and PARA 82 et seq post.

18 See the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105 (as amended); and PARA 204 post.

19 See the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322 (as amended); and PARA 212 et seq post.

20 See the Blood Safety and Quality Regulations 2005, SI 2005/50 (as amended); and PARA 185 et seq post.

21 See the Medical Devices Regulations 2002, SI 2002/618 (as amended); and PARA 231 et seq post.

UPDATE

1 The scope of control

NOTES 16, 19--SI 1994/3142, SI 1997/322 revoked: SI 2005/2745.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(1) INTRODUCTION/2. Consumer protection.

2. Consumer protection.

The Medicines Act 1968 makes it an offence to adulterate a medicinal product¹ or to sell an adulterated medicinal product or a medicinal product not of the nature or quality demanded by the purchaser². Products sold under or by reference to names appearing at the head of monographs in the British Pharmacopoeia³ or in other specified compendia must comply with the standards specified in those compendia⁴.

Provision is made for the ministers⁵ to control by regulations the colours, shapes and markings of medicinal products, and to control the containers in which medicinal products may be sold, the labelling and marking of those containers and packages, and the contents of any leaflets supplied with such products⁶.

The Act makes it illegal to issue a false or misleading advertisement relating to a medicinal product and imposes other controls upon the promotion of the sale of medicinal products⁷. The ministers, as the licensing authority, may require copies of advertisements to be sent to them, and may make regulations controlling advertisements and representations⁸.

Provision is made for the enforcement of the Act and its regulations by the ministers, the drugs authority for each area, and the Pharmaceutical Society⁹. Rights of entry and power to take samples and to seize goods and documents are conferred upon authorised officers of enforcement authorities¹⁰, and a procedure for the testing and analysis of samples is specified¹¹.

1 For the meaning of 'medicinal product' see PARA 7 post.

2 See the Medicines Act 1968 ss 63, 64, 67 (as amended); and PARAS 146-147 post.

3 As to the publication of the British Pharmacopoeia and other compendia, including a European Pharmacopoeia, see *ibid* Pt VII (ss 99-103); and PARA 149 et seq post.

4 See *ibid* s 65 (as amended); and PARA 148 post.

5 For the meaning of 'the ministers' see PARA 3 note 3 post.

6 See the Medicines Act 1968 Pt V (ss 85-91) (as amended); and PARA 152 et seq post.

7 See *ibid* Pt VI (ss 92-97) (as amended); and PARA 157 et seq post.

8 See *ibid* ss 95, 97 (both as amended); and PARAS 158, 166 post.

9 See *ibid* s 108 (as amended); and PARA 168 post. 'Pharmaceutical Society', in relation to Great Britain, means the Pharmaceutical Society of Great Britain: s 132(1). As to the Pharmaceutical Society of Great Britain see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 881 et seq. For the meaning of 'Great Britain' see PARA 7 note 3 post.

10 See *ibid* ss 111-114 (s 114 as amended); and PARA 169 et seq post.

11 See *ibid* ss 112, 113, Sch 3 (as amended); and PARAS 170-171 post. As to the analysis of products by the public analyst see s 115; and PARA 171 post.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(1) INTRODUCTION/3. The ministers responsible.

3. The ministers responsible.

The administration and enforcement of the provisions of the Medicines Acts 1968 and 1971¹ regulating dealings with medicinal products² is generally in the hands of 'the ministers'³, that is, 'the health ministers'⁴ and 'the agriculture ministers'⁵. Except where the contrary is expressly provided, 'the appropriate ministers', for the purpose of performing any function⁶ where the function is performed exclusively in relation to matters other than veterinary drugs⁷ and the treatment of diseases⁸ of animals, means the health ministers⁹, and in any other case means the ministers generally¹⁰.

1 The Medicines Act 1968 and the Medicines Act 1971 may be cited together as the Medicines Acts 1968 and 1971: Medicines Act 1971 s 2(1). The Medicines Act 1971 amends the Medicines Act 1968 and makes further provision for the payment of fees under Pt II (ss 6-50) (as amended): see PARA 44 et seq post.

2 For the meaning of 'medicinal product' see PARA 7 post.

3 'The ministers' means the Secretary of State and the Minister of Health and Social Services for Northern Ireland and the Minister of Agriculture for Northern Ireland (see notes 4, 5 infra); and, in the case of anything falling to be done by the ministers, means all those ministers acting jointly: Medicines Act 1968 s 1(1) (amended by the Ministry of Agriculture, Fisheries and Food (Dissolution) Order 2002, SI 2002/794, art 5(1), (2), Sch 1 para 15(1), (3), Sch 2). In any enactment, 'Secretary of State' means one of Her Majesty's principal Secretaries of State: see the Interpretation Act 1978 s 5, Sch 1. As to the office of Secretary of State see CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARA 355. As to the interpretation of references to ministries of Northern Ireland see the Northern Ireland Act 1998 s 95(5), Sch 12; and CONSTITUTIONAL LAW AND HUMAN RIGHTS.

4 'The health ministers' means the Secretary of State concerned with health in England and the Minister of Health and Social Services for Northern Ireland; and, in the case of anything falling to be done by the health ministers, means those ministers acting jointly: Medicines Act 1968 s 1(1)(a) (amended by the Transfer of Functions (Medicines and Poisons) Order 1999, SI 1999/3142, art 5, Schedule para 1(1)). See also note 3 supra. For the meaning of 'England' see PARA 7 note 3 post. As to the Secretary of State for Health see CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARA 464. As to the establishment of the medicines and healthcare products regulatory agency trading fund in connection with certain operations in relation to medicinal products of the Department of Health under the Medicines Acts 1968 and 1971, subordinate legislation made thereunder and certain other legislation, see the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003, SI 2003/1076 (amended by SI 2005/2061). As to government trading funds generally see CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARA 743 et seq.

5 'The agriculture ministers' means the Secretary of State for Environment, Food and Rural Affairs and the Minister of Agriculture for Northern Ireland; and, in the case of anything falling to be done by the agriculture ministers, means those ministers acting jointly: Medicines Act 1968 s 1(1)(b) (amended by the Transfer of Functions (Medicines and Poisons) Order 1999, SI 1999/3142, Schedule para 1(1); and the Ministry of Agriculture, Fisheries and Food (Dissolution) Order 2002, SI 2002/794, Sch 1 para 15(1), (2)). See also note 3 supra. As to the Secretary of State for Environment, Food and Rural Affairs see CONSTITUTIONAL LAW AND HUMAN RIGHTS.

6 Ie any function under the Medicines Act 1968, whether by the making of any regulations or order or otherwise: s 1(2)(a). As to the making of orders or regulations see PARA 5 post.

7 'Veterinary drug' means a medicinal product which is manufactured, sold, supplied, imported or exported for the purpose of being administered to animals, but not for the purpose of being administered to human beings; and 'animal' includes any bird, fish or reptile: ibid s 132(1). For the meaning of 'administer' see PARA 7 note 2 post.

8 As to the meaning of 'disease' see PARA 8 note 2 post.

9 Medicines Act 1968 ss 1(2)(a), 132(1).

10 Ibid ss 1(2)(b), 132(1).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(1) INTRODUCTION/4. Advice to the ministers.

4. Advice to the ministers.

The Commission on Human Medicines¹ is established to give to any one or more of the health ministers² or the agriculture ministers³ advice on matters relating to the Medicines Act 1968, certain regulations⁴, and medicinal products⁵ generally⁶. The ministers⁷, the health ministers or the agriculture ministers may establish specialist committees for any purpose connected with the execution of the Act or the exercise of any power conferred by it, including advising as to the safety, quality or efficacy of medicinal products⁸. The Commission must appoint expert advisory groups to advise on the safety, quality and efficacy of certain medicinal products⁹. When acting as the licensing authority¹⁰, the ministers may not, on grounds relating to safety, quality or efficacy, refuse to grant¹¹ or renew a licence¹² or an animal test certificate¹³, or suspend, revoke or vary a licence¹⁴ or certificate¹⁵ already granted, except after consultation with the appropriate committee¹⁶.

Before prohibiting the sale, supply or importation of a medicinal product on the ground that it is necessary to do so in the interests of safety, the appropriate ministers¹⁷ must consult the appropriate committee unless in the opinion of those ministers it is essential that an order be made with immediate effect to avoid serious danger to health¹⁸. Where any ministers propose to make any regulations or order¹⁹ relating to dealings with medicinal products²⁰, containers, packages and identification of such products²¹, or advertising²², or under the provisions enabling them to apply the statutory provisions to substances other than medicinal products²³, and they consult either a committee or the Commission with respect to the proposal, they must take the advice of the committee or of the Commission into account before proceeding with their proposal²⁴.

1 As to the Commission on Human Medicines see PARA 13 et seq post.

2 For the meaning of 'the health ministers' see PARA 3 note 4 ante.

3 For the meaning of 'the agriculture ministers' see PARA 3 note 5 ante.

4 I.e. the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, and the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031 (as amended).

5 For the meaning of 'medicinal product' see PARA 7 post.

6 See the Medicines Act 1968 s 3 (as substituted); and PARA 14 post.

7 For the meaning of 'the ministers' see PARA 3 note 3 ante.

8 See the Medicines Act 1968 s 4 (as amended); and PARA 15 post.

9 See *ibid* s 5 (as amended), Sch 1A (as added); and PARA 17 post.

10 As to the licensing authority see *ibid* s 6; and PARA 43 post.

11 See *ibid* s 20(3) (as amended); and PARA 61 post.

12 See *ibid* s 24(4) (as amended); and PARA 68 post.

13 See *ibid* ss 36(3), 38(5) (both as amended); and PARAS 130-131 post.

14 See *ibid* s 29(1), Sch 2 para 1 (as substituted); and PARA 73 post.

15 See *ibid* s 39(3) (as amended); and PARA 132 post.

16 See the provisions referred to in notes 10-15 *supra*. Those provisions do not, however, apply in case of urgency: see PARA 76 post. For the meaning of 'the appropriate committee' see PARA 15 note 5 post.

17 For the meaning of 'the appropriate ministers' see PARA 3 ante.

18 See the Medicines Act 1968 s 62(3) (as amended); and PARA 48 post.

19 As to the making of regulations and orders see PARA 5 post.

20 *Ie* under the Medicines Act 1968 Pt III (ss 51-68): see PARA 133 et seq post.

21 *Ie* under *ibid* Pt V (ss 85-91): see PARA 152 et seq post.

22 *Ie* under *ibid* Pt VI (ss 92-97): see PARA 157 et seq post.

23 *Ie* under *ibid* ss 104, 105 (both as amended): see PARA 9 post.

24 *Ibid* s 129(7).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(1) INTRODUCTION/5. Orders and regulations.

5. Orders and regulations.

Where the Medicines Act 1968 authorises or requires regulations to be made for any purpose, the regulations are to be made by the ministers¹, unless the specific provision states otherwise². Any power to make orders³ or regulations⁴ under the Act is exercisable by statutory instrument⁵. Any power to make regulations may be exercised so as to make different provision for different areas or in relation to different cases or different circumstances, and to make any such provision subject to any exceptions, limitations or conditions which may be considered necessary or expedient⁶. Before making any regulations or order⁷ under the Act, the ministers proposing to make the order or regulations must consult such organisations as appear to them to be representative of interests likely to be substantially affected by the regulations or order⁸.

1 For the meaning of 'the ministers' see PARA 3 note 3 ante.

2 Medicines Act 1968 s 129(1). In relation to the making of regulations and orders, the knowledge of civil servants cannot be imputed to ministers, and ministers must know or be told enough to ensure that nothing that it is necessary, because legally relevant, for them to know is left out of account, although this does not mean that they must know everything that is relevant; what it is relevant for them to know is enough to enable them to make an informed judgment: *R (on the application of National Association of Health Stores) v Secretary of State for Health* [2005] EWCA Civ 154, [2005] All ER (D) 324 (Feb). In the absence of any public interest in non-disclosure, a briefing to a minister in respect of a proposed regulation or order should be disclosed in litigation contesting the regulation or order: *R (on the application of National Association of Health Stores) v Secretary of State for Health* supra at [49] per Sedley LJ. As to disclosure of documents see CIVIL PROCEDURE vol 11 (2009) PARA 749 et seq.

3 Ie other than an order made by a court or judge, or certain orders relating to Northern Ireland: Medicines Act 1968 s 129(2).

4 Ie other than certain regulations relating to Northern Ireland: see *ibid* s 129(2).

5 *Ibid* s 129(2). This provision applies also to the Medicines Act 1971 s 1 (see PARA 11 post): s 1(3)(b)). Any statutory instrument consisting of:

- 1 (1) an order made under the Medicines Act 1968 s 13 (see PARA 54 post), s 15(1) (see PARA 49 post), s 35(2)(b) (see PARA 49 post), s 49 (see PARA 12 post), s 54(2) (see PARA 136 post), s 55(2) (as amended) (see PARA 137 post), s 56 (see PARA 138 post), s 57(1) (see PARA 139 post), s 58 (as amended) (see PARA 140 post), s 62 (see PARA 48 post), s 106 (see PARA 7 note 11 post), s 116 (as amended) (see PARA 173 post), s 117 (as amended) (see PARA 171 post), s 130(5)(c) (see PARA 7 post), Sch 3 para 27 (see PARA 171 post) (s 129(3)(a));
- 2 (2) an order made under s 105 (as amended) (see PARA 9 post) otherwise than as mentioned in s 105(3) (s 129(3)(b)); or
- 3 (3) any regulations made under the Act (s 129(3)(c)),

is subject to annulment in pursuance of a resolution of either House of Parliament: s 129(3). Section 129(3)(c) applies also to the Medicines Act 1971 s 1: s 1(3)(b). As to the annulment of statutory instruments see STATUTES vol 44(1) (Reissue) PARA 1516.

Any power to make an order under any provision of the Medicines Act 1968 other than s 16(1) (see PARAS 44 note 7, 46 note 7, 47 note 12 post), s 17 (termination of transitional exemptions), ss 25(1), 37(3) (both repealed), s 52 (see PARA 134 post), includes power to revoke or vary the order by a subsequent order: s 129(4).

6 *Ibid* s 129(5). This provision applies also to the Medicines Act 1971 s 1: s 1(3)(b).

7 Ie except an order made in accordance with any provision of the Medicines Act 1968 under which, in case of urgency, an order can be made with immediate effect: s 129(6).

8 Ibid s 129(6). This provision applies also to the Medicines Act 1971 s 1: s 1(3)(b). The organisations to be consulted include, where any provisions of the regulations or order apply to veterinary products as defined in the Food Standards Act 1999 s 29(2), the Food Standards Agency: Medicines Act 1968 s 129(6A) (added by the Food Standards Act 1999 s 18, Sch 3 Pt III para 15(1), (3)). As to the Food Standards Agency see FOOD vol 18(2) (Reissue) PARA 225 et seq. As to the ministers' duty in certain cases to take into account any advice received from the Commission on Human Medicines or a committee see the Medicines Act 1968 s 129(7); and PARA 4 ante.

UPDATE

5 Orders and regulations

TEXT AND NOTE 6--1968 Act s 129(5) amended: Health Act 2006 s 32 (not yet in force).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(1) INTRODUCTION/6. Powers to regulate dealings with medicinal products.

6. Powers to regulate dealings with medicinal products.

The appropriate ministers¹ may prescribe by regulations² such requirements as they consider necessary or expedient with respect to any of the following matters:

- 1 (1) the manner in which or persons under whose supervision medicinal products³ may be prepared or dispensed⁴;
- 2 (2) the amount of space to be provided in any premises for persons preparing or dispensing medicinal products, the separation of any such space from the remainder of the premises, and the facilities to be provided in any premises for such persons⁵;
- 3 (3) the amount of space to be provided in any premises for the sale or supply of medicinal products⁶;
- 4 (4) the accommodation⁷ to be provided in any premises for members of the public to whom medicinal products are sold or supplied or for whom they are being prepared or assembled⁸;
- 5 (5) the amount of space to be provided in any premises for the storage of medicinal products⁹;
- 6 (6) the safekeeping of medicinal products¹⁰;
- 7 (7) the disposal of unusable or otherwise unwanted medicinal products¹¹;
- 8 (8) precautions to be observed before medicinal products are sold or supplied¹²;
- 9 (9) the keeping of records relating to the sale or supply of medicinal products¹³;
- 10 (10) the supply of medicinal products distributed as samples¹⁴;
- 11 (11) sanitation, cleanliness, temperature, humidity or other factors relating to the risks of deterioration or contamination in connection with the manufacture¹⁵, storage, transportation, sale or supply of medicinal products¹⁶; and
- 12 (12) the construction, location and use of automatic machines for the sale of medicinal products¹⁷.

The regulations may prescribe requirements in respect of: (a) the construction, lay-out, drainage, equipment, maintenance, ventilation, lighting and water supply of premises at or from which medicinal products are manufactured, stored, transported, sold or supplied¹⁸; (b) the disposal of refuse at or from such premises¹⁹; and (c) any apparatus, equipment, furnishings or utensils used at any such premises²⁰.

Any such regulations may provide that any person who contravenes²¹ the regulations is guilty of an offence and liable on summary conviction to a fine²².

1 For the meaning of 'the appropriate ministers' see PARA 3 ante.

2 The following regulations have been made under the Medicines Act 1968 s 66(1): the Medicines (Advertising) Regulations 1994, SI 1994/1932 (amended by SI 1994/3144; SI 1996/1552; SI 1999/267; SI 2002/236; SI 2003/2321; SI 2004/1480; SI 2005/2787); and the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980, SI 1980/1923 (amended by SI 1982/28; SI 1990/1124; SI 1990/2487; SI 1992/2938; SI 1994/2411; SI 1994/3142; SI 1994/3144; SI 1995/3215; SI 1997/1831; SI 1997/2045; SI 1998/1045; SI 1999/644; SI 1999/2510; SI 2000/7; SI 2000/1070; SI 2000/1918; SI 2000/2494; SI 2001/3849; SI 2002/2469; SI 2003/698; SI 2004/696; SI 2004/1771; SI 2005/764; SI 2005/1520; SI 2005/2750). As to the making of regulations see PARA 5 ante.

3 For the meaning of 'medicinal product' see PARA 7 post.

- 4 Medicines Act 1968 s 66(1)(a).
- 5 Ibid s 66(1)(b).
- 6 Ibid s 66(1)(c).
- 7 This includes the amount of space: ibid s 66(1)(d).
- 8 Ibid s 66(1)(d). 'Assemble', in relation to a medicinal product, means enclosing the product (with or without other medicinal products of the same description) in a container which is labelled before the product is sold or supplied or, where the product (with or without such other medicinal products) is already enclosed in the container in which it is to be sold or supplied, labelling the container before the product is sold or supplied in it, and 'assembly' has a corresponding meaning: s 132(1). As to medicinal products of the same description see PARA 7 note 33 post. For the meanings of 'container' and 'labelling' see PARA 152 note 4 post.
- 9 Ibid s 66(1)(e).
- 10 Ibid s 66(1)(f).
- 11 Ibid s 66(1)(g).
- 12 Ibid s 66(1)(h).
- 13 Ibid s 66(1)(i).
- 14 Ibid s 66(1)(j).
- 15 As to the meaning of 'manufacture' see PARA 7 note 2 post.
- 16 Medicines Act 1968 s 66(1)(k).
- 17 Ibid s 66(1)(l). For other provisions relating to automatic machines see PARA 136 post.
- 18 Ibid s 66(2)(a).
- 19 Ibid s 66(2)(b).
- 20 Ibid s 66(2)(c).
- 21 'Contravention' includes failure to comply, and 'contravene' has a corresponding meaning: ibid s 132(1).
- 22 Ibid s 67(6) (amended by virtue of the Criminal Justice Act 1982 ss 38, 46). This provision is subject to the Medicines Act 1968 ss 121, 122 (see PARAS 179-180 post): s 67(1). The fine is to be a fine not exceeding level 5 on the standard scale or such lesser sum as may be specified in the regulations: see s 67(6) (as so amended). The court has certain powers of disqualification in respect of persons convicted of such an offence: see s 68; and PARA 182 post. 'Standard scale' means the standard scale of maximum fines for summary offences as set out in the Criminal Justice Act 1982 s 37 (as amended): see the Interpretation Act 1978 s 5, Sch 1 (definition added by the Criminal Justice Act 1988 s 170(1), Sch 15 para 58); and SENTENCING AND DISPOSITION OF OFFENDERS vol 92 (2010) PARA 142. At the date at which this volume states the law, the standard scale is as follows: level 1, £200; level 2, £500; level 3, £1,000; level 4, £2,500; level 5, £5,000: Criminal Justice Act 1982 s 37(2) (substituted by the Criminal Justice Act 1991 s 17(1)). As to the determination of the amount of the fine actually imposed, as distinct from the level on the standard scale which it may not exceed, see the Criminal Justice Act 2003 s 164; and MAGISTRATES vol 29(2) (Reissue) PARA 807.

UPDATE

6 Powers to regulate dealings with medicinal products

NOTE 2--SI 1980/1923 further amended: SI 2005/2745, SI 2006/914, SI 2007/289, SI 2007/2179, SI 2007/3101, SI 2008/1162, SI 2009/3063.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(1) INTRODUCTION/7. Meaning of 'medicinal product'.

7. Meaning of 'medicinal product'.

'Medicinal product' means any substance¹ or article (not being an instrument, apparatus or appliance) which is manufactured², sold, supplied, imported³ or exported⁴ for use wholly or mainly in either or both of the following ways⁵: (1) use by being administered to one or more human beings or animals for a medicinal purpose⁶; or (2) use, in specified circumstances, as an ingredient⁷ in the preparation of a substance or article which is to be administered to one or more human beings or animals for a medicinal purpose⁸. The specified circumstances are use in a pharmacy or hospital⁹, use by a practitioner¹⁰, and use in the course of a business¹¹ which consists of or includes the retail sale¹², or the supply in circumstances corresponding to retail sale¹³, of herbal remedies¹⁴. An order made by the agriculture ministers¹⁵ may provide that any specified description or class of medicated feeding stuff¹⁶ is to be treated as a medicinal product¹⁷, or is not to be so treated¹⁸.

However, 'medicinal product' does not include any substance or article which is manufactured for use wholly or mainly by being administered to one or more human beings or animals, where it is to be administered to them:

- 13 (a) in the course of the business of the person who has manufactured it ('the manufacturer'), or on behalf of the manufacturer in the course of the business of a laboratory or research establishment carried on by another person¹⁹; and
- 14 (b) solely by way of a test for ascertaining what effects it has when so administered²⁰; and
- 15 (c) in circumstances where the manufacturer has no knowledge of any evidence that those effects are likely to be beneficial to those human beings, or beneficial to, or otherwise advantageous in relation to, those animals, as the case may be²¹,

and which, having been so manufactured, is not sold, supplied or exported for use wholly or mainly in any way not fulfilling all of the conditions specified in heads (a) to (c) above²².

'Medicinal product' must also be taken not to include substances used in dental surgery for filling dental cavities²³, bandages and other surgical dressings (except medicated dressings²⁴), whole human blood and human blood components²⁵, and substances and articles of such other descriptions or classes as may be specified by an order made by the ministers, the health ministers²⁶ or the agriculture ministers²⁷.

Where, in accordance with these provisions, a substance or article is a medicinal product immediately after it has been manufactured, imported or exported²⁸, or immediately after it has been sold or supplied²⁹, it does not cease to be a medicinal product by reason only that it is subsequently sold, supplied, imported or exported wholly or mainly in a way other than one specified³⁰ above³¹.

Medicinal products are of the same description if, but only if, they are manufactured to the same specification³² and they are, or are to be, sold, supplied, imported or exported in the same pharmaceutical form³³.

1 'Substance' means any natural or artificial substance, whether in solid or liquid form or in the form of a gas or vapour: Medicines Act 1968 s 132(1).

2 'Manufacture', in relation to a medicinal product, includes any process carried out in the course of making the product, but does not include dissolving or dispersing the product in, or diluting or mixing it with, some

other substance used as a vehicle for the purpose of administering it and does not include the incorporation of the product in any animal feeding stuff: *ibid* s 132(1). 'Animal feeding stuff' means any substance which is intended for use either by being fed to one or more animals or as an ingredient in the preparation of such a substance, not being in either case a medicinal product: s 132(1). 'Administer' means administer to a human being or an animal, whether orally, by injection or by introduction into the body in any other way, or by external application, whether by direct contact with the body or not; and any reference to administering or feeding a substance or article is a reference to administering or feeding it either in its existing state or after it has been dissolved or dispersed in, or diluted or mixed with, some other substance used as a vehicle: s 130(9) (amended by the Animal Health and Welfare Act 1984 s 16, Sch 1 para 3, Sch 2). As to the meaning of 'animal' see PARA 3 note 7 ante.

3 'Import' means import into the United Kingdom, whether by land, sea or air: Medicines Act 1968 s 132(1). As to the time when importation and exportation via the Channel Tunnel is deemed to have occurred see the Channel Tunnel (Customs and Excise) Order 1990, SI 1990/2167. 'United Kingdom' means Great Britain and Northern Ireland: Interpretation Act 1978 s 5, Sch 1. 'Great Britain' means England, Scotland and Wales: Union with Scotland Act 1706, preamble art I; Interpretation Act 1978 s 22(1), Sch 2 para 5(a). Neither the Channel Islands nor the Isle of Man are within the United Kingdom. See further CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARA 3. 'England' means, subject to any alteration of boundaries of local government areas, the area consisting of the counties established by the Local Government Act 1972 s 1 (see LOCAL GOVERNMENT vol 69 (2009) PARA 23 et seq), Greater London and the Isles of Scilly: Interpretation Act 1978 s 5, Sch 1. 'Wales' means the combined area of the counties which were created by the Local Government Act 1972 s 20 (as originally enacted) (see LOCAL GOVERNMENT vol 69 (2009) PARA 37), but subject to any alteration made under s 73 (as amended) (consequential alteration of boundary following alteration of watercourse) (see LOCAL GOVERNMENT vol 69 (2009) PARA 90): Interpretation Act 1978 Sch 1 (definition substituted by the Local Government (Wales) Act 1994 s 1(3), Sch 2 para 9). As to local government areas see LOCAL GOVERNMENT vol 69 (2009) PARA 22 et seq; and as to boundary changes see LOCAL GOVERNMENT vol 69 (2009) PARA 56 et seq. As to Greater London see LONDON GOVERNMENT vol 29(2) (Reissue) PARA 29.

4 'Export' means export from the United Kingdom, whether by land, sea or air: Medicines Act 1968 s 132(1). See also note 3 supra.

5 *Ibid* s 130(1).

6 *Ibid* s 130(1)(a). For the meaning of 'a medicinal purpose' see PARA 8 post.

7 'Ingredient', in relation to the manufacture or preparation of a substance, includes anything which is the sole active ingredient of that substance as manufactured or prepared: *ibid* s 132(1).

8 *Ibid* s 130(1)(b). Alcohol which is, or is included in, a medicinal product is not alcohol for the purposes of the Licensing Act 2003: see s 191(1)(e), (2); and LICENSING AND GAMBLING vol 67 (2008) PARA 30.

9 Medicines Act 1968 s 130(3)(a). 'Hospital' includes a clinic, nursing home or similar institution: s 132(1).

10 *Ibid* s 130(3)(b). 'Practitioner' (except where that word occurs as part of the expression 'veterinary practitioner') means a doctor, dentist, veterinary surgeon or veterinary practitioner: s 132(1). 'Doctor' means a registered medical practitioner within the meaning of the Interpretation Act 1978 Sch 1 (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 4): Medicines Act 1968 s 132(1) (definition substituted by the Medical Act 1983 s 56(1), Sch 5 para 5). 'Dentist' means a person registered in the dentists register under the Dentists Act 1984 or entered in the list of visiting EEA practitioners under Sch 4 (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARAS 417 et seq, 431): Medicines Act 1968 s 132(1) (definition amended by the Dental Qualifications (Recognition) Regulations 1996, SI 1996/1496, reg 7(a)). 'Veterinary practitioner' means a person registered in the supplementary veterinary register kept under the Veterinary Surgeons Act 1966 s 8; and 'veterinary surgeon' means a person registered in the register of veterinary surgeons kept under the Veterinary Surgeons Act 1966 s 2 (as amended): Medicines Act 1968 s 132(1). As to registration under the Veterinary Surgeons Act 1966 ss 2, 8 (s 2 as amended) see ANIMALS vol 2 (2008) PARAS 1133-1134.

11 'Business' includes a professional practice and includes any activity carried on by a body of persons, whether corporate or unincorporate: Medicines Act 1968 s 132(1). As to bodies corporate and unincorporated bodies see COMPANIES; CORPORATIONS. The ministers may by order direct that such provisions of the Medicines Act 1968 as may be specified in the order, in so far as they relate to things done by a person in the course of a business carried on by him, have effect, subject to such exceptions and modifications as may be specified in the order, as if in those provisions any reference to a business included a reference to an activity (other than a business) of a description specified in the order: s 106(1). Without prejudice to s 106(1), the ministers may by order direct that such provisions of the Act as may be specified in the order, in so far as they relate to things done by a person in the course of a business carried on by him, have effect, subject to such exceptions and modifications as may be specified in the order, as if, in such circumstances as may be so specified, a business carried on by a person's employer were a business carried on by that person: s 106(2). For the meaning of 'the

ministers' see PARA 3 note 3 ante. At the date at which this volume states the law, no such order had been made. As to the making of orders see PARA 5 ante.

12 Any reference to selling by retail, or to retail sale, is a reference to selling a substance or article to a person as being a person who buys it otherwise than for the purposes of:

4 (1) selling or supplying it; or

5 (2) administering it or causing it to be administered to one or more human beings,

in the course of a business carried on by that person: *ibid* s 131(3). See also s 131(5) (amended by the National Health Service Act 1977 s 129, Sch 15 para 49; the National Health Service (Scotland) Act 1978 s 109, Sch 16 para 30; and the National Health Service Reorganisation Act 1973 ss 57, 58, Sch 4 para 128(2)).

13 Any reference to 'supplying anything in circumstances corresponding to retail sale' is a reference to supplying it, otherwise than by way of sale, to a person as being a person who receives it for a purpose other than that of:

6 (1) selling or supplying it; or

7 (2) administering it or causing it to be administered to one or more human beings,

in the course of a business carried on by that person: Medicines Act 1968 s 131(4). See also note 12 *supra*.

14 *Ibid* s 130(3)(c). 'Herbal remedy' means a medicinal product consisting of a substance produced by subjecting a plant or plants to drying, crushing or any other process, or of a mixture whose sole ingredients are two or more substances so produced, or of a mixture whose sole ingredients are one or more substances so produced and water or some other inert substance; and 'plant' includes any part of a plant: s 132(1).

15 No such order may be made unless a draft of the order has been laid before Parliament and approved by resolution of each House of Parliament: *ibid* s 130(3C) (s 130(3A)-(3C) added by the Animal Health and Welfare Act 1984 s 13(2)). As to the laying of documents before Parliament see PARLIAMENT vol 34 (Reissue) PARA 941. For the meaning of 'the agriculture ministers' see PARA 3 note 5 ante.

16 For these purposes, 'medicated feeding stuff' means any substance which is manufactured, sold, supplied, imported or exported for use wholly or mainly in either or both of the following ways: (1) use by being fed to one or more animals for a medicinal purpose or for purposes that include that purpose; or (2) use as an ingredient in the preparation of a substance which is to be fed to one or more animals for a medicinal purpose or for purposes that include that purpose: Medicines Act 1968 s 130(3B) (as added: see note 15 *supra*).

17 *Ibid* s 130(3A)(a) (as added: see note 15 *supra*). At the date at which this volume states the law no such order had been made. As to regulations relating to medicated feeding stuffs see AGRICULTURAL PRODUCTION AND MARKETING vol 1 (2008) PARA 996 et seq.

18 *Ibid* s 130(3A)(b) (as added: see note 15 *supra*). See also note 17 *supra*.

19 *Ibid* s 130(4)(a).

20 *Ibid* s 130(4)(b).

21 *Ibid* s 130(4)(c).

22 *Ibid* s 130(4) (amended by the Animal Health and Welfare Act 1984 Sch 1 para 3, Sch 2).

23 Medicines Act 1968 s 130(5)(a). See also the Medicines (Dental Filling Substances) Order 1975, SI 1975/533 (as amended), which directs that specified provisions of the Act have effect in relation to dental filling substances, subject to specified exemptions and modifications; and PARA 9 post.

24 Medicines Act 1968 s 130(5)(b) (s 130(5)(b) amended, and s 130(5A) added, by the Medical Devices (Consequential Amendments--Medicines) Regulations 1994, SI 1994/3119, reg 2). Medicated dressings are not excluded from the definition of 'medicinal product' by the Medicines Act 1968 s 130(5)(b) (as amended) if their medication has a curative function which is not limited to sterilising the dressing, and they are not dressings of a kind to which the requirements of EC Council Directive 93/42 (OJ L169, 12.7.1993, p 1) art 2 (placing medical devices on the market and putting them into service) apply or would apply but for art 4 (devices intended for special purposes) or art 22 (transitional provisions): Medicines Act 1968 s 130(5A) (as so added).

25 *Ibid* s 130(5)(ba) (s 130(5)(ba), (5B) added by the Blood Safety and Quality Regulations 2005, SI 2005/50, reg 25(1)(c), (d)). For these purposes, 'human blood component' means any of the following constituents of human blood: red cells, white cells, platelets and plasma: Medicines Act 1968 s 130(5B) (as so added).

26 For the meaning of 'the health ministers' see PARA 3 note 4 ante.

27 Medicines Act 1968 s 130(5)(c). Orders have been made under this provision directing that specified substances are not to be treated as medicinal products: see the Medicines (Breathing Gases) Order 1977, SI 1977/1488 (oxygen, air, any mixture of the two, or of either or both with any inert gas or gases, whether compressed or not, in specified circumstances); and the Medicines (Chemical Sterilants) Order 1986, SI 1986/2177 (chemical substances used to sterilise, permanently or temporarily, animals which are not domesticated or held in captivity).

28 Ie as mentioned in the Medicines Act 1968 s 130(1) (see the text to notes 1-8 supra) and s 130(3B) (as added) (see note 16 supra).

29 See note 28 supra.

30 Ie specified in the provisions referred to in note 28 supra.

31 Medicines Act 1968 s 130(6) (amended by the Animal Health and Welfare Act 1984 Sch 1 para 3, Sch 2).

32 Medicines Act 1968 s 130(8)(a).

33 Ibid s 130(8)(b). 'Description', in relation to medicinal products, is to be construed accordingly: s 130(8).

UPDATE

7 Meaning of 'medicinal product'

NOTES--Certain functions under provisions mentioned in this paragraph are 'relevant functions' for the purposes of the Regulatory Enforcement and Sanctions Act 2008 s 4, Sch 3, see LOCAL GOVERNMENT vol 69 (2009) PARA 733.

NOTE 12--1968 Act s 131(5) further amended: National Health Service (Consequential Provisions) Act 2006 Sch 1 para 44.

NOTE 27--SI 1986/2177 revoked: SI 2005/2745.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(1) INTRODUCTION/8. Meaning of 'a medicinal purpose'.

8. Meaning of 'a medicinal purpose'.

'A medicinal purpose' is any one or more of the following: (1) treating¹ or preventing disease²; (2) diagnosing disease or ascertaining the existence, degree or extent of a physiological condition³; (3) contraception⁴; (4) inducing anaesthesia⁵; (5) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating, reducing or postponing, or increasing or accelerating, the operation of that function or in any other way⁶.

1 'Treatment', in relation to disease, includes anything done or provided for alleviating the effects of the disease, whether it is done or provided by way of cure or not: Medicines Act 1968 s 132(1).

2 Ibid s 130(2)(a). 'Disease' includes any injury, ailment or adverse condition, whether of body or mind: s 132(1).

3 Ibid s 130(2)(b).

4 Ibid s 130(2)(c).

5 Ibid s 130(2)(d).

6 Ibid s 130(2)(e).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(1) INTRODUCTION/9. Application of provisions to non-medicinal products.

9. Application of provisions to non-medicinal products.

The ministers¹, the health ministers² or the agriculture ministers³ may specify by order⁴ any description or class of articles or substances⁵ appearing to them to be articles or substances which are not medicinal products⁶ but are manufactured, sold, supplied, imported⁷ or exported⁸ for use wholly or partly for a medicinal purpose⁹, and may direct that, subject to such exceptions and modifications as may be specified in the order, specified provisions of the Medicines Act 1968 or the clinical trials regulations¹⁰, including provisions which relate to offences or penalties, are to have effect in relation to articles or substances of that description or class as they have effect in relation to medicinal products¹¹.

The ministers may also specify by order¹² any substance appearing to them to be a substance which is not itself a medicinal product but which is used as an ingredient¹³ in the manufacture¹⁴ of medicinal products¹⁵, or which if used without proper safeguards is capable of causing danger to the health of the community, or of causing danger to the health of animals generally or of one or more species of animals¹⁶, and direct that, subject to such exceptions and modifications as may be specified in the order, specified provisions of the Act or the clinical trials regulations are to have effect in relation to that substance as they have effect in relation to medicinal products¹⁷. This power may be exercised in relation to a class of substances if it appears to the ministers that the conditions¹⁸ are fulfilled in relation to all substances falling within the class¹⁹.

1 For the meaning of 'the ministers' see PARA 3 note 3 ante.

2 For the meaning of 'the health ministers' see PARA 3 note 4 ante.

3 For the meaning of 'the agriculture ministers' see PARA 3 note 5 ante.

4 No such order may be made unless a draft of the order has been laid before Parliament and approved by a resolution of each House of Parliament: Medicines Act 1968 s 104(2). As to the laying of documents before Parliament see PARLIAMENT vol 34 (Reissue) PARA 941. As to the making of orders see PARA 5 ante.

5 For the meaning of 'substance' see PARA 7 note 1 ante.

6 For the meaning of 'medicinal product' see PARA 7 ante.

7 For the meaning of 'import' see PARA 7 note 3 ante.

8 For the meaning of 'export' see PARA 7 note 4 ante.

9 For the meaning of 'a medicinal purpose' see PARA 8 ante.

10 'The clinical trials regulations' means the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031 (as amended); Medicines Act 1968 s 132(1) (definition added by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 54, Sch 10 Pt 1 para 19(a)(ii)). As to such regulations see PARA 82 et seq post.

11 Medicines Act 1968 s 104(1) (amended by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, Sch 10 Pt 1 para 17). For orders made under the Medicines Act 1968 s 104 see the Medicines (Surgical Materials) Order 1971, SI 1971/1267 (amended by SI 1994/3119; SI 2004/1031) (specified surgical ligatures or sutures or absorbable materials); the Medicines (Dental Filling Substances) Order 1975, SI 1975/533 (amended by SI 1994/3119; SI 2004/1031); the Medicines (Specified Articles and Substances) Order 1976, SI 1976/968 (amended by SI 1994/3119; SI 2004/1031) (contact lenses, contact lens fluids and associated substances and intra-uterine contraceptive devices); the Medicines (Radioactive Substances) Order 1978, SI

1978/1004 (radioactive substances for insertion into or contact with the body, and administration for tests); and the Medicines (Cyanogenetic Substances) Order 1984, SI 1984/187 (preparations of or containing amygdalin, laetrile, vitamin B17, or containing specified cyanide-producing substances).

12 Any statutory instrument consisting of an order made under the Medicines Act 1968 s 105 otherwise than as mentioned in s 105(3) (see note 16 *infra*) is subject to annulment in pursuance of a resolution of either House of Parliament: s 129(3)(b). As to the making of orders see PARA 5 *ante*. As to the annulment of statutory instruments see STATUTES vol 44(1) (Reissue) PARA 1516.

13 As to the meaning of 'ingredient' see PARA 7 note 7 *ante*.

14 As to the meaning of 'manufacture' see PARA 7 note 2 *ante*.

15 Medicines Act 1968 s 105(1)(a).

16 *Ibid* s 105(1)(b). As to the meaning of 'animal' see PARA 3 note 7 *ante*. No order may be made in relation to a substance as being a substance in respect of which the condition specified in s 105(1)(b) is fulfilled (s 105(3)(a)), or in relation to a class of substances as being substances in respect of which that condition is fulfilled (s 105(3)(b)), unless a draft of the order has been laid before Parliament and approved by a resolution of each House of Parliament (s 105(3)). See also the text to notes 18-19 *infra*.

17 *Ibid* s 105(1) (amended by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, Sch 10 Pt 1 para 18). For orders under the Medicines Act 1968 s 105(1) see the Medicines (Control of Substances for Manufacture) Order 1971, SI 1971/1200; the Medicines (Extension to Antimicrobial Substances) Order 1973, SI 1973/367 (amended by SI 2005/2754); and the Medicines (Control of Substances for Manufacture) Order 1985, SI 1985/1403 (amended by SI 1994/787).

18 *Ie* the conditions specified in the Medicines Act 1968 s 105(1)(a) or (b): see the text and notes 12-16 *supra*.

19 *Ibid* s 105(2).

UPDATE

9 Application of provisions to non-medicinal products

NOTE 17--SI 1971/1200, SI 1973/367, SI 1985/1403 amended: SI 2005/2745.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(1) INTRODUCTION/10. The operation and effect of the Medicines Act 1968.

10. The operation and effect of the Medicines Act 1968.

The provisions of the Medicines Act 1968 and of any regulations or order made under it¹ operate cumulatively, and any exemption or exception from any of those provisions is not to be construed as conferring any exemption or exception in relation to any other of those provisions². Except in so far as the Act expressly provides otherwise, and subject to the statutory provisions³ relating to offences under two or more laws, the provisions of the Act do not confer any right of action in any civil proceedings (other than proceedings for recovery of a fine) in respect of any contravention⁴ of the Act or of any regulations or order made under it⁵, or affect any restrictions⁶ imposed by or under any other enactment⁷, or derogate from any right of action or other remedy, civil or criminal, in proceedings instituted otherwise than under the Act⁸. No exemption conferred by or under any provision of the Act derogates from any exemption or immunity of the Crown⁹.

1 As to the making of regulations and orders see PARA 5 ante.

2 Medicines Act 1968 s 133(1).

3 I.e. the Interpretation Act 1978 s 18: see STATUTES vol 44(1) (Reissue) PARA 1445.

4 For the meaning of 'contravention' see PARA 6 note 21 ante.

5 Medicines Act 1968 s 133(2)(a). As to the effect of s 133(2) in respect of claims in tort see *Smith v Secretary of State for Health* [2002] EWHC 200 (QB), 67 BMLR 34.

6 I.e. whether contained in a public general Act or in a local or private Act: Medicines Act 1968 s 133(2)(b).

7 Ibid s 133(2)(b).

8 Ibid s 133(2)(c). See note 5 supra.

9 Ibid s 133(3). As to Crown immunity see CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARA 382 et seq; CROWN AND ROYAL FAMILY vol 12(1) (Reissue) PARAS 47-48, 52 et seq; CROWN PROCEEDINGS vol 12(1) (Reissue) PARA 101 et seq; STATUTES vol 44(1) (Reissue) PARA 1321. A visiting force or headquarters, members of such a force or headquarters, persons employed in the service of such a force, and property used for the purposes of such a force or headquarters, are exempt from the operation of the Medicines Act 1968 to the extent that, by virtue of the rule of law whereby enactments do not bind the Crown, such a force or headquarters, such members, such persons, or such property, would be so exempt if the force or headquarters were a part of any of the home forces: Visiting Forces and International Headquarters (Application of Law) Order 1999, SI 1999/1736, art 12(1), Sch 5. As to the forces and headquarters to which the order applies see art 3, Schs 1, 2.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(1) INTRODUCTION/11. Financial provisions.

11. Financial provisions.

There must be defrayed out of money provided by Parliament any expenses incurred by any of the health ministers¹ or the agriculture ministers² in consequence of the Medicines Acts 1968 and 1971³, and any increase attributable to the provisions of the Medicines Act 1968 in respect of certain grants to local authorities⁴. Expenses incurred by the Pharmaceutical Society⁵ or any other body in enforcing⁶ any provision of the Medicines Act 1968 or any regulations or order made thereunder must be repaid by the minister who has a concurrent duty to enforce the provision in question⁷.

With the consent of the Treasury⁸, the ministers⁹ may make regulations¹⁰ providing for:

- 16 (1) the payment and recovery of prescribed fees: (a) in connection with applications under the Medicines Act 1968 for a licence, certificate or direction¹¹ or the variation or renewal of a licence or certificate¹²; or (b) in respect of inspections made in connection with applications for licences or during the currency of any such licence¹³;
- 17 (2) the payment and recovery of: (a) prescribed annual or periodic fees (in addition to inspection fees) in connection with the holding of a licence; or (b) penalty for failure to pay such a fee in time¹⁴;
- 18 (3) the calculation of any such annual or periodic fee by reference to the United Kingdom turnover¹⁵ of the medicinal products¹⁶ to which the licence relates or of all such products to which licences held by the holder relate, or the fees received by the holder in respect of the medicinal product or products to which the licence relates or in respect of all the medicinal products to which licences held by the holder relate¹⁷;
- 19 (4) the calculation of any such annual or periodic fee in a manner specified, where no or insufficient evidence is submitted to enable the calculation set out in head (3) above to be made¹⁸;
- 20 (5) the payment of any fee by instalments, and the refund, adjustment, set-off, waiver or reduction of fees¹⁹; and
- 21 (6) the suspension of any licence or certificate while the fee remains unpaid²⁰.

Any fees received by the ministers by virtue of the Medicines Acts 1968 and 1971 must be paid into the Exchequer²¹.

1 For the meaning of 'the health ministers' see PARA 3 note 4 ante.

2 For the meaning of 'the agriculture ministers' see PARA 3 note 5 ante.

3 Medicines Act 1968 s 128(1); Medicines Act 1971 s 1(3)(a). This does not include expenses so incurred exclusively in respect of executing the Acts in Northern Ireland: Medicines Act 1968 s 128(1); Medicines Act 1971 s 1(3)(a).

4 Medicines Act 1968 s 128(2)(a). This provision refers to rate support grants which may arise from the inclusion, in the expenditure relevant to the fixing of the aggregate amount of those grants, of expenditure under the Medicines Act 1968 (see s 128(2)(a)), but rate support grants have been replaced by revenue support grants (see LOCAL GOVERNMENT vol 29(1) (Reissue) PARA 531 et seq).

5 For the meaning of 'Pharmaceutical Society' see PARA 2 note 9 ante.

6 le under the Medicines Act 1968 s 108(2): see PARA 168 post.

7 See *ibid* s 128(4).

8 As to the Treasury see CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARAS 512-517.

9 For the meaning of 'the ministers' see PARA 3 note 3 ante.

10 The Medicines Act 1968 s 129(2), (3)(c), (5), (6) (which provide for regulations to be subject to annulment and contain other supplementary provisions relating to such regulations: see PARA 5 ante) apply to such regulations: Medicines Act 1971 s 1(3)(b). As to the regulations that have been made see the Medicines (Products for Human Use--Fees) Regulations 1995, SI 1995/1116 (amended by SI 1996/683; SI 1998/574; SI 1999/566; SI 2000/592; SI 2000/3031; SI 2001/795; SI 2002/236; SI 2002/542; SI 2003/625; SI 2003/2321; SI 2004/666; SI 2004/1157; SI 2005/1124); and the Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750 (amended by SI 2004/3081).

11 le under the Medicines Act 1968 Pt II (ss 6-50) (as amended). In the Medicines Act 1971 s 1(1), (2)(b) (see the text to note 20 *infra*) any reference to a licence under the Medicines Act 1968 Pt II (as amended) includes a reference to a manufacturing authorisation under the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031 (as amended): Medicines Act 1971 s 1(2A) (added by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 54, Sch 10 para 20). As to the licensing provisions see PARA 44 *et seq post*. As to authorisations in respect of clinical trials see PARA 90 *et seq post*. As to animal test certificates see PARA 130 *et seq post*.

12 Medicines Act 1971 s 1(1)(a). See note 11 *supra*.

13 *Ibid* s 1(1)(aa) (s 1(1)(aa)-(ad), (1A) added, and s 1(1)(b) amended, by the Health and Medicines Act 1988 s 21). See note 11 *supra*.

14 See the Medicines Act 1971 s 1(1)(ab) (as added: see note 13 *supra*). See also note 11 *supra*.

15 'United Kingdom turnover' means the value, determined under the regulations, of the aggregate of all quantities of a medicinal product (see note 16 *infra*) other than quantities excluded by the regulations, which, during a specified period: (1) in the case of a product licence (see PARA 44 *post*), are sold or supplied in the United Kingdom by the holder of a licence or other prescribed person; (2) in the case of a manufacturer's licence (see PARA 46 *post*), are manufactured or assembled in the United Kingdom by the holder; (3) in the case of a wholesale dealer's licence (see PARA 47 *post*), are sold by way of wholesale dealing in the United Kingdom: *ibid* s 1(1A) (as added: see note 13 *supra*). As to the meaning of 'manufacture' see PARA 7 note 2 ante. For the meaning of 'assemble' see PARA 6 note 8 ante. For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

16 For these purposes, 'medicinal product' includes: (1) substances or articles to which provisions of the Medicines Act 1968 Pt II (as amended) have been extended under s 104 (as amended) or s 105 (as amended) (see PARA 9 ante); and (2) medicated feeding stuffs which are to be treated as medicinal products under s 130(3B) (as added) (see PARA 7 note 16 ante): Medicines Act 1971 s 1(1A) (as added: see note 13 *supra*). For the meaning of 'medicinal product' for the purposes of the Medicines Act 1968 see PARA 7 ante.

17 Medicines Act 1971 s 1(1)(ac) (as added: see note 13 *supra*).

18 *Ibid* s 1(1)(ad) (as added: see note 13 *supra*).

19 *Ibid* s 1(1)(b) (as amended: see note 13 *supra*).

20 *Ibid* s 1(2)(b). See note 11 *supra*.

21 Medicines Act 1968 s 128(6); Medicines Act 1971 s 1(3)(a). As to the Exchequer see CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARA 711.

UPDATE

11 Financial provisions

NOTE 10--SI 1995/1116 replaced: see now the Medicines (Products for Human Use) (Fees) Regulations 2009, SI 2009/389 (amended by SI 2009/3222).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(1) INTRODUCTION/12. Postponement of restrictions in relation to exports.

12. Postponement of restrictions in relation to exports.

Subject to certain exceptions¹, in relation to anything done before the special appointed day² the licensing provisions of the Medicines Act 1968³ have effect as if every reference to exportation⁴ were omitted⁵, any reference to the sale or supply of a medicinal product⁶ did not include sale or supply which involves, or is for the purposes of, exporting the product⁷, and any reference to offering a medicinal product for sale did not include an offer for sale where the prospective sale would involve, or would be for the purposes of, exporting the product⁸.

The ministers must not make an order appointing such a day unless it appears to them to be necessary or expedient to do so for the purpose of giving effect to an agreement to which the United Kingdom⁹ or the United Kingdom government is a party or will be a party on the day appointed by the order¹⁰.

Where an order has been made, transitional provisions¹¹ apply, unless they are expressly excluded by the order¹², in relation to certain medicinal products; and in certain circumstances a product licence¹³ limited in various ways may be granted where transitional conditions are satisfied¹⁴. A product licence in force on the special appointed day is extended in certain circumstances to cover exportation¹⁵.

The provisions exempting acts done before the special appointed day do not affect the operation of the licensing provisions in relation to any medicinal product falling within a class specified in an order made by the health ministers¹⁶ or the agriculture ministers¹⁷. No class of medicinal products may be specified in such an order unless it appears to the ministers making the order to be requisite to do so for securing that any exemption conferred does not apply to medicinal products consisting wholly or partly of substances¹⁸ the purity or potency of which cannot, in their opinion, adequately be tested by chemical means¹⁹. The provisions requiring a product licence²⁰ did not have effect in relation to a person in respect of his exporting, or procuring the exportation of, medicinal products of any description falling within a class specified in an order which was in force immediately before the first appointed day²¹ if transitional conditions were satisfied²². Where those transitional provisions were satisfied a person might apply for and be granted a product licence of right, limited in various ways²³.

¹ See under the Medicines Act 1968 s 49 (see the text and notes 16-23 infra), s 49A (as added) (see note 5 infra).

² 'The special appointed day' means such day subsequent to 1 September 1971 (being the first appointed day: see *ibid* s 16(1); and the Medicines (First Appointed Day) Order 1971, SI 1971/1153) as the ministers may by order appoint for the purposes of the Medicines Act 1968 s 48: s 48(1). For the meaning of 'the ministers' see PARA 3 note 3 ante. No such order may be made unless a draft of the order has been laid before Parliament and approved by resolution of each House of Parliament: s 48(10). At the date at which this volume states the law, no such order had been made. As to the laying of documents before Parliament see PARLIAMENT vol 34 (Reissue) PARA 941. As to the making of orders see PARA 5 ante.

³ See *ibid* ss 7-47: see PARA 44 et seq post.

⁴ For the meaning of 'export' see PARA 7 note 4 ante.

⁵ Medicines Act 1968 s 48(1)(a). Nothing in s 48(1) affects the operation of s 8(3A) (as added) (see PARA 47 post) in relation to the exportation of a product, or the sale or supply of a product which involves, or is for the purposes of, the exportation of the product if it is a product to which European Parliament and Council Directive EC 2001/83 (OJ L311, 28.11.2001, p 67) on the Community code relating to medicinal products for human use (as amended) applies and the exportation is, or is to be, to a member state: Medicines Act 1968 s 49A (added

by the Medicines Act 1968 (Amendment) Regulations 1993, SI 1993/834, reg 6; and amended by the Medicines (Codification Amendments Etc) Regulations 2002, SI 2002/236, reg 2(a)(iv)); Medicines Act 1968 s 132(1) (definition added by the Medicines (Codification Amendments Etc) Regulations 2002, SI 2002/236, reg 2(d)(ii); and amended by the Medicines for Human Use (Fees and Miscellaneous Amendments) Regulations 2003, SI 2003/2321, reg 2). For the meaning of 'member state' see the European Communities Act 1972 s 1(2), Sch 1 Pt II; and the Interpretation Act 1978 s 5, Sch 1.

6 For the meaning of 'medicinal product' see PARA 7 ante.

7 Medicines Act 1968 s 48(1)(b).

8 Ibid s 48(1)(c).

9 For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

10 Medicines Act 1968 s 48(2).

11 See ibid s 48(3).

12 See ibid s 48(4).

13 For the meaning of 'product licence' see PARA 44 note 5 post.

14 See the Medicines Act 1968 s 48(5).

15 See ibid s 48(6). A person who is entitled to a licence under s 48(6) and also a licence of right under s 25(1) (see note 23 infra) in respect of medicinal products of a particular description may apply for a single product licence for both purposes, and he is entitled to a product licence having the same effect as the two licences, if granted separately, would have had: s 48(7). An order made under s 48(1) (see the text and notes 1-8 supra) may contain appropriate provisions relating to licence applications: s 48(9).

16 For the meaning of 'the health ministers' see PARA 3 note 4 ante.

17 Medicines Act 1968 s 49(1). For the meaning of 'the agriculture ministers' see PARA 3 note 5 ante. The following order has been made under s 49: the Medicines (Exportation of Specified Veterinary Products) Order 1971, SI 1971/1309.

18 For the meaning of 'substance' see PARA 7 note 1 ante.

19 Medicines Act 1968 s 49(2). The provisions of s 48(3)-(7) (see the text to notes 11-15 supra) do not have effect in relation to medicinal products of any description falling within a class specified in an order under s 49 which is in force immediately before the special appointed day: s 49(3).

20 Ie ibid s 7(2): see PARA 44 post.

21 See note 2 supra.

22 See the Medicines Act 1968 s 49(4), (5). As to the order that has been made under s 49 see note 17 supra.

23 See ibid s 49(6)-(8). Licences of right could be granted on applications made before 1 July 1972 if the applicant satisfied conditions in the transitional provisions (see s 16(2)-(5)): see s 25(1), (2) (repealed); and the Medicines (Closing Date for Applications for Licences of Right) Order 1972, SI 1972/717. No closing date in relation to dental filling substances has been fixed: see the Medicines (Dental Filling Substances) Order 1975, SI 1975/533, art 2. 'Licence of right' includes such a licence which has been renewed, but not a new licence granted in its place: Medicines Act 1968 s 25(4). The procedure for applications is laid down by s 27.

UPDATE

12 Postponement of restrictions in relation to exports

NOTE 5--1968 Act s 49A repealed: Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005, SI 2005/2789. Nothing in the 1968 Act s 48 affects the operation of s 8(3A) (see PARA 47) in relation to the exportation of a product, or the sale or supply of a product which involves, or is for the

purposes of, the exportation of the product if (1) it is a product to which European Parliament and EC Council Directive 2001/83 on the Community code relating to medicinal products for human use applies; and (2) the exportation is, or is to be, to an EEA State: 1968 Act s 49B (added by SI 2005/2789). 'EEA State' means a member state, Norway, Iceland or Liechtenstein: 1968 Act s 132 (definition added by SI 2005/2789). 1968 Act s 132(1) further amended: SI 2008/3097.

NOTE 17--SI 1971/1309 revoked: SI 2005/2745.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(2) THE COMMISSION ON HUMAN MEDICINES/13. Constitution.

(2) THE COMMISSION ON HUMAN MEDICINES

13. Constitution.

A body of persons called the Commission on Human Medicines¹ is established to perform the functions assigned to the Commission by or under the Medicines Act 1968². The ministers³ appoint the members of the Commission⁴ which must have at least eight members⁵. The ministers must appoint the chairmen of the biologicals expert advisory group, the chemistry, pharmacy and standards expert advisory group and the pharmacovigilance expert advisory group⁶ as members of the Commission, and must appoint one of the members of the Commission to be its chairman⁷. Subject to the approval of the Secretary of State, at any meeting of an advisory body⁸, that body may co-opt additional members⁹. A co-opted member holds office only in relation to the meeting for which he is co-opted¹⁰.

1 In the Medicines Act 1968, the Commission on Human Medicines is referred to as 'the Commission': s 2A(1) (s 2A added by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, regs 3, 6); Medicines Act 1968 s 132(1) (definition amended by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 8, Sch 1 para 14(b)). The Commission replaces the Medicines Commission established under the Medicines Act 1968 s 2 (repealed) which was abolished on 30 October 2005: see the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 2. On 30 October 2005, all property, rights and liabilities to which the Medicines Commission was entitled or subject immediately before that date transferred to the Secretary of State: reg 12. As to the Commission see further PARA 16 post. As to the Secretary of State see PARA 3 note 3 ante.

2 Medicines Act 1968 s 2A(1) (as added: see note 1 supra). As to the Commission's functions see PARA 14 post.

3 For the meaning of 'the ministers' see PARA 3 note 3 ante.

4 Medicines Act 1968 s 2A(2) (as added: see note 1 supra).

5 Ibid s 2A(3) (as added: see note 1 supra). Members of the Commission are disqualified for membership of the House of Commons: see the House of Commons Disqualification Act 1975 s 1(1)(f), Sch 1 Pt II (amended by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 10, Sch 3); and PARLIAMENT vol 78 (2010) PARA 905 et seq.

6 Medicines Act 1968 s 2A(4) (as added: see note 1 supra). As to expert advisory groups see PARA 17 post.

7 Ibid s 2A(5) (as added: see note 1 supra).

8 'Advisory body' means the Commission or a committee established under ibid s 4 (as amended) (see PARA 15 post): s 5(1), Sch 1A para 1 (s 5 amended, and Sch 1A added, by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, regs 6, 7(2)); Medicines Act 1968 s 132(1) (definition added by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, Sch 1 para 14(a)).

9 Medicines Act 1968 Sch 1A para 2(1) (as added: see note 8 supra).

10 Ibid Sch 1A para 2(2) (as added: see note 8 supra).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(2) THE COMMISSION ON HUMAN MEDICINES/14. Functions.

14. Functions.

The Commission on Human Medicines¹, where either it considers it expedient or it is requested by the minister or ministers in question to do so, must give to any one or more of the health ministers² or the agriculture ministers³ advice on matters: (1) relating to the execution of, or the exercise of any power conferred by, the Medicines Act 1968⁴; (2) relating to the execution of, or the exercise of any power conferred by, the marketing authorisation regulations⁵ the clinical trials regulations⁶, the homoeopathic regulations⁷, or the herbal regulations⁸; or (3) otherwise relating to medicinal products⁹. Without prejudice to this duty, and to any other duties or powers imposed or conferred on the Commission¹⁰, it is the duty of the Commission to:

- 22 (a) give advice with respect to safety, quality or efficacy in relation to medicinal products¹¹;
- 23 (b) promote the collection and investigation of information relating to adverse reactions, for the purposes of enabling such advice to be given¹²; and
- 24 (c) undertake functions¹³ in relation to the British Pharmacopoeia, any compendium or list of names or other publication¹⁴,

except in so far as those functions are for the time being assigned to a committee¹⁵. The Commission must also advise the licensing authority¹⁶ in cases where the authority: (i) is required¹⁷ to consult the Commission with respect to any matter¹⁸; or (ii) without being required to do so, elects to consult the Commission with respect to any matter¹⁹.

The ministers²⁰, after consultation with the Commission, may by order²¹: (A) add to, revoke or vary any of the statutory provisions²² in their application to the Commission²³; (B) confer on the Commission any new function for purposes connected with medicinal products or related matters²⁴; (C) terminate any function conferred on the Commission by or under the Act²⁵; or (D) vary any such function²⁶.

The Commission must, at such time in each year as the ministers may direct, send to the health ministers and the agriculture ministers a report with respect to the performance of its functions²⁷ and the performance of functions by any expert advisory group appointed by it²⁸, including any such group which is jointly appointed by it and another advisory body or bodies²⁹.

1 As to the constitution of the Commission see PARA 13 ante. As to the possibility of bringing a claim in negligence against the Commission in respect of the exercise of its functions see *Smith v Secretary of State for Health* [2002] EWHC 200 (QB), 67 BMLR 34.

2 For the meaning of 'the health ministers' see PARA 3 note 4 ante.

3 For the meaning of 'the agriculture ministers' see PARA 3 note 5 ante.

4 Medicines Act 1968 s 3(1)(a), (b) (s 3 substituted by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 4).

5 'The marketing authorisation regulations' means the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144 (as amended) (see PARA 20 et seq post): Medicines Act 1968 s 132(1) (definition added by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 8, Sch 1 para 14(e)).

6 For the meaning of 'the clinical trials regulations' see PARA 9 note 10 ante.

7 'The homoeopathic regulations' means the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105 (as amended) (see PARA 205 et seq post); Medicines Act 1968 s 132(1) (definition added by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 8, Sch 1 para 14(d)).

8 Medicines Act 1968 s 3(1)(c), (d) (as substituted (see note 4 supra); s 3(1)(c) further substituted by the Medicines (Advisory Bodies) (No 2) Regulations 2005, SI 2005/2754, reg 2, Sch 1 para 1(2)). 'The herbal regulations' means the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, SI 2005/2750 (see PARA 230 post); Medicines Act 1968 s 132(1) (definition added by the Medicines (Advisory Bodies) (No 2) Regulations 2005, SI 2005/2754, Sch 1 para 3).

9 Medicines Act 1968 s 3(1)(e) (as substituted: see note 4 supra). For the meaning of 'medicinal product' see PARA 7 ante. Any function of the Commission relating to product licences applies to marketing authorisations for veterinary medicinal products in the same way as it applies to licences: Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 18(3). As to product licences see PARA 44 post. As to marketing authorisations for veterinary medicinal products see PARA 34 et seq post.

10 Ie by or under the Medicines Act 1968, the marketing authorisation regulations, the homoeopathic regulations, the herbal regulations or the clinical trials regulations: Medicines Act 1968 s 3(2) (as substituted (see note 4 supra); and further amended by the Medicines (Advisory Bodies) (No 2) Regulations 2005, SI 2005/2754, Sch 1 para 3(a)).

11 Medicines Act 1968 s 3(2)(a)(i) (as substituted: see note 4 supra).

12 Ibid s 3(2)(a)(ii) (as substituted: see note 4 supra).

13 Ie the functions mentioned in ibid s 4(4): see PARA 15 post.

14 Ibid s 3(2)(a)(iii) (as substituted: see note 4 supra).

15 Ibid s 3(2)(a) (as substituted: see note 4 supra). As to committees see PARA 15 post.

16 For the meaning of 'the licensing authority' see PARA 43 note 8 post.

17 Ie by the provisions of the Medicines Act 1968 Pt II (ss 6-50) (as amended) (see PARA 44 et seq post) or by the provisions of the marketing authorisation regulations, the homoeopathic regulations, the herbal regulations or the clinical trial regulations.

18 Ibid s 3(2)(b)(i) (as substituted (see note 4 supra); and further amended by the Medicines (Advisory Bodies) (No 2) Regulations 2005, SI 2005/2754, Sch 1 para 3(b)).

19 Medicines Act 1968 s 3(2)(b)(ii) (as substituted: see note 4 supra). The matters referred to in the text are any matters arising under the provisions mentioned in note 15 supra.

20 For the meaning of 'the ministers' see PARA 3 note 3 ante.

21 No such order may be made unless a draft of the order has been laid before Parliament and approved by a resolution of each House of Parliament: Medicines Act 1968 s 5(5). At the date at which this volume states the law, no such order had been made. As to the laying of documents before Parliament see PARLIAMENT vol 34 (Reissue) PARA 941. As to the making of orders see PARA 5 ante.

22 Ie the provisions of ibid Sch 1A (as added): see PARAS 13 ante, 16-17 post.

23 Ibid s 5(4)(a) (amended by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 6(5)).

24 Medicines Act 1968 s 5(4)(b).

25 Ibid s 5(4)(c).

26 Ibid s 5(4)(d). Such variation may not, however, confer on the Commission any new function which could not be conferred on it in accordance with head (b) in the text: s 5(4)(d).

27 Ibid s 5(2)(a) (s 5(2) substituted by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 6(3)).

28 Ie under the Medicines Act 1968 s 5(1) (as amended), Sch 1A para 3 (as added): see PARA 17 post.

29 Ibid s 5(2)(b) (as substituted: see note 25 supra). For the meaning of 'advisory body' see PARA 13 note 8 ante. The Secretary of State must lay before Parliament a copy of every such report: s 5(2) (as so substituted). As to the Secretary of State see PARA 3 note 3 ante.

UPDATE

14 Functions

NOTE 9--SI 1994/3142 revoked: SI 2005/2745.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(2) THE COMMISSION ON HUMAN MEDICINES/15. Committees.

15. Committees.

The ministers¹, the health ministers² or the agriculture ministers³ may by order⁴ establish one or more committees⁵ for any purpose, or combination of purposes, connected with:

- 25 (1) the execution of the Medicines Act 1968, the marketing authorisation regulations, the homoeopathic regulations, the herbal regulations or the clinical trials regulations⁶; or
- 26 (2) the exercise of any power conferred by the Act or those regulations⁷,

either generally or in relation to any particular class of substances⁸ or articles to which any provision of the Act or those regulations applies⁹. In particular, in relation to any such class of substances or articles, a committee may be established for either or both of the purposes of: (a) giving advice with respect to safety, quality or efficacy, or with respect to all or any two of those matters¹⁰; (b) promoting the collection and investigation of information relating to adverse reactions, for the purpose of enabling such advice to be given¹¹. A committee or committees may be established for the purpose of performing any function¹² in relation to the British Pharmacopoeia or in relation to any such compendium or list of names or other publication¹³.

A committee must have at least eight members¹⁴, with the ministers by whom a committee is established appointing the members of the committee and appointing one of those members to be chairman of the committee¹⁵.

Each committee must, at such time in each year as the ministers may direct, send to the health ministers and the agriculture ministers a report with respect to the performance of its functions¹⁶, and the performance of functions by any expert advisory group appointed¹⁷ by it, including any expert advisory group which is jointly appointed by it and another advisory body or bodies¹⁸.

1 For the meaning of 'the ministers' see PARA 3 note 3 ante.

2 For the meaning of 'the health ministers' see PARA 3 note 4 ante.

3 For the meaning of 'the agriculture ministers' see PARA 3 note 5 ante.

4 As to the orders that have been made see the Medicines (Committee on Safety of Medicines) Order 1970, SI 1970/1257; the Medicines (Veterinary Products Committee) Order 1970, SI 1970/1304; the Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1995, SI 1995/309 (as amended) (see PARA 204 post); the Herbal Medicines Advisory Committee Order 2005, SI 2005/2791. See also note 13 infra. As to the making of orders see PARA 5 ante.

5 Medicines Act 1968 s 4(1) (amended by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 5(1), (2)). As to committees see further PARA 16 post.

In the Medicines Act 1968, 'the appropriate committee', for the purposes of any provision of the Act under which a function falls to be performed, means: (1) in a case where a committee has been established under s 4 (as amended) for purposes which consist of or include any of those specified in s 4(3) (see the text to notes 10-11 infra) and the authority performing that function considers it to be the appropriate committee in the circumstances, that committee (s 4(6)(a) (s 4(6) substituted by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 5(1), (5))); and (2) in any other case, the Commission on Human Medicines (Medicines Act 1968 s 4(6)(b) (as so substituted)). As to the constitution of the Commission see PARA 13 ante.

6 Ibid s 4(2)(a) (s 4(2) amended, and s 4(2)(a), (b) added, by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 54, Sch 10 Pt 1 para 2; and the Medicines Act 1968 s 4(2)(a) amended by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 5(1), (3), and the Medicines (Advisory Bodies) (No 2) Regulations 2005, SI 2005/2754, reg 2, Sch 1 para 1(2)). For the meaning of 'the marketing authorisation regulations' see PARA 14 note 5 ante; for the meaning of 'the homoeopathic regulations' see PARA 14 note 7 ante; and for the meaning of 'the herbal regulations' see PARA 14 note 8 ante. For the meaning of 'the clinical trials regulations' see PARA 9 note 10 ante.

7 Medicines Act 1968 s 4(2)(b) (as added: see note 6 supra).

8 For the meaning of 'substance' see PARA 7 note 1 ante.

9 Medicines Act 1968 s 4(2) (as amended: see note 6 supra). Any function of a committee relating to product licences applies to marketing authorisations for veterinary medicinal products in the same way as it applies to licences: Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 18(3). As to product licences see PARA 44 post. As to marketing authorisations for veterinary medicinal products see PARA 34 et seq post.

10 Medicines Act 1968 s 4(3)(a). In relation to any substance or article, considerations of safety must be taken to include consideration of the extent (if any) to which the substance or article:

- 8 (1) if used without proper safeguards, is capable of causing danger to the health of the community, or of causing danger to the health of animals generally or of one or more species of animals (s 132(2)(a)); or
- 9 (2) if administered to an animal, may be harmful to the animal or may induce disease in other animals or may leave a residue in the carcase or produce of the animal which may be harmful to human beings (s 132(2)(b)); or
- 10 (3) may interfere with the treatment, prevention or diagnosis of disease (s 132(2)(c)); or
- 11 (4) may be harmful to the person administering it or (in the case of an instrument, apparatus or appliance) the person operating it (s 132(2)(d)),

and any reference to safety or to the interests of safety is to be construed accordingly: s 132(2). As to the meaning of 'administer' see PARA 7 note 2 ante. As to the meaning 'animal' see PARA 3 note 7 ante. As to the meaning 'disease' see PARA 8 note 2 ante.

11 Ibid s 4(3)(b).

12 Ie under ibid Pt VII (ss 99-103) (as amended): see PARA 149 et seq post.

13 Ibid s 4(4). See the Medicines (British Pharmacopoeia Commission) Order 1970, SI 1970/1256 (amended by SI 1982/1335).

14 Medicines Act 1968 s 4(4A) (added by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 5(1), (4)). The members of a committee are disqualified for membership of the House of Commons: see the House of Commons Disqualification Act 1975 s 1(1)(f), Sch 1 Pt II (amended by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 10, Sch 3); and PARLIAMENT vol 78 (2010) PARA 905 et seq.

15 Medicines Act 1968 s 4(5). As to the power of a committee to co-opt members see PARA 13 ante. Where a committee is established for purposes including the consideration of veterinary products as defined in the Food Standards Act 1999 s 29(2), one member of the committee must be appointed by the ministers establishing the committee on the nomination of the Food Standards Agency: Medicines Act 1968 s 4(5A) (added by the Food Standards Act 1999 s 18, Sch 3 Pt III para 15(1), (2)). As to the Food Standards Agency see FOOD vol 18(2) (Reissue) PARA 225 et seq.

16 Medicines Act 1968 s 5(3)(a) (s 5(3) substituted by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 6(4)).

17 Ie under the Medicines Act 1968 s 5(1) (as amended), Sch 1A para 3 (as added): see PARA 17 post.

18 Ibid s 5(3)(b) (as substituted: see note 16 supra). For the meaning of 'advisory body' see PARA 13 note 8 ante. The Secretary of State must lay before Parliament a copy of every such report: s 5(3) (as so substituted). As to the Secretary of State see PARA 3 note 3 ante. As to the laying of documents before Parliament see PARLIAMENT vol 34 (Reissue) PARA 941.

UPDATE

15 Committees

NOTE 4--SI 1970/1304 revoked: SI 2005/2745. The Veterinary Products Committee is continued in force by the Veterinary Medicines Regulations 2009, SI 2009/2297, reg 28.

NOTE 9--SI 1994/3142 revoked: SI 2005/2745.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(2) THE COMMISSION ON HUMAN MEDICINES/16. General provisions relating to the Commission on Human Medicines and committees.

16. General provisions relating to the Commission on Human Medicines and committees.

The ministers¹ may make provision by regulations² with respect to the terms on which members of advisory bodies³ hold and vacate office, including the terms on which any person appointed as chairman of such a body must hold and vacate office as chairman⁴. A member of an advisory body holds and vacates office in accordance with the terms of the instrument by which he is appointed⁵, and a chairman of an advisory body holds and vacates office as chairman in accordance with the terms of the instrument by which he is appointed as chairman⁶. A member's term of office must not exceed four years⁷, and a chairman's term of office must not exceed the remainder of his term as a member of the advisory body⁸. A member may resign office, and a chairman may resign from the office of chairman, at any time by notice in writing to the ministers⁹. Where a person ceases to be a member of an advisory body, he also ceases to be a member of any expert advisory group¹⁰ appointed by that advisory body, including any group appointed jointly with another advisory body¹¹.

The ministers may pay to the members of each advisory body such remuneration (if any) and such allowances as may be determined by the ministers with the consent of the Treasury¹². The ministers must provide each advisory body with such staff and such accommodation, services and other facilities as appear to the ministers to be necessary or expedient for the proper performance of its functions¹³, and must defray any expenses incurred with their approval by each advisory body¹⁴.

An advisory body may, subject to approval by the Secretary of State¹⁵, make such provision as it thinks fit to regulate its own proceedings¹⁶. The validity of any proceedings of an advisory body is not affected by a vacancy among the members of that advisory body¹⁷, or a defect in the appointment of any member of that body¹⁸.

No advisory body is to be taken to be the servant or agent of the Crown or to enjoy any status or immunity of the Crown¹⁹.

1 For the meaning of 'the ministers' see PARA 3 note 3 ante.

2 As to the making of regulations see PARA 5 ante. As to the regulations that have been made see the Medicines (Advisory Bodies) (Terms of Office of Members) Regulations 2005, SI 2005/2788; and the text to notes 5-11 infra.

3 For the meaning of 'advisory body' see PARA 13 note 8 ante.

4 Medicines Act 1968 s 5(1), Sch 1A para 6(a) (s 5(1) amended, and Sch 1A added, by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, regs 6(1), 7).

5 Medicines (Advisory Bodies) (Terms of Office of Members) Regulations 2005, SI 2005/2788, reg 2(1).

6 Ibid reg 3(1).

7 Ibid reg 2(2).

8 Ibid reg 3(2).

9 Ibid regs 2(3), 3(3). As to the service of notices see PARA 37 note 8 post.

10 As to expert advisory groups see PARA 17 post.

11 Medicines (Advisory Bodies) (Terms of Office of Members) Regulations 2005, SI 2005/2788, reg 2(4). However, reg 2(4) does not apply where the person was a member of the advisory body only by virtue of being co-opted under the Medicines Act 1968 Sch 1A para 2 (as added) (see PARA 13 ante) or where the person is immediately re-appointed to the advisory body: Medicines (Advisory Bodies) (Terms of Office of Members) Regulations 2005, SI 2005/2788, reg 2(5).

12 Medicines Act 1968 Sch 1A para 10 (as added: see note 4 supra). As to the Treasury see CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARAS 512-517. As to the defraying of expenses under the Medicines Act 1968 see PARA 11 ante.

13 Ibid Sch 1A para 7 (as added: see note 4 supra).

14 Ibid Sch 1A para 11 (as added: see note 4 supra).

15 As to the Secretary of State see PARA 3 note 3 ante.

16 Medicines Act 1968 Sch 1A para 9(1) (as added: see note 4 supra).

17 Ibid Sch 1A para 8(a) (as added: see note 4 supra).

18 Ibid Sch 1A para 8(b) (as added: see note 4 supra).

19 Ibid Sch 1A para 12 (as added: see note 4 supra).

UPDATE

16 General provisions relating to the Commission on Human Medicines and committees

NOTE 4--Medicines Act 1968 Sch 1A para 6 renumbered as para 6(1); regulations made under Sch 1A para 6(1) may include such incidental, supplemental, consequential or transitional provision as appears to the ministers to be expedient: Sch 1A para 6(2) (Sch 1A para 6 amended by the Health Act 2009 Sch 3 para 1).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(2) THE COMMISSION ON HUMAN MEDICINES/17. Expert advisory groups.

17. Expert advisory groups.

An advisory body¹, or any two or more advisory bodies acting jointly, may, subject to the approval of the Secretary of State², appoint sub-committees to be known as expert advisory groups³. The Secretary of State may direct an advisory body to appoint an expert advisory group to advise on such matters as may be specified in the direction⁴. An expert advisory group may include or consist of persons who are not members of the advisory body or bodies which appointed that group⁵. With certain exceptions⁶, the advisory body or bodies which appointed the expert advisory group must appoint one of the members of the group as chairman⁷. At any meeting of an expert advisory group, the chairman of that group may, after consulting the chairman or chairmen of the advisory body or bodies which appointed that group, co-opt additional members of that group⁸. The co-opted members hold office only in relation to the meeting for which they are co-opted⁹. The ministers may make provision by regulations¹⁰ with respect to the terms on which members of expert advisory groups hold and vacate office¹¹, including the terms on which any person appointed as chairman of such a group must hold and vacate office as chairman¹²; and the ministers must defray any expenses incurred with their approval by an expert advisory group¹³. The Secretary of State may make such provision as he thinks fit to regulate the proceedings of expert advisory groups¹⁴. The validity of any proceedings of an expert advisory group is not affected by a vacancy among the members of that group¹⁵, or a defect in the appointment of any such member¹⁶. No expert advisory group is to be taken to be the servant or agent of the Crown or to enjoy any status or immunity of the Crown¹⁷.

An advisory body may delegate to an expert advisory group such of its functions as it thinks fit¹⁸, with the exception of any function which consists of advising the licensing authority¹⁹ in cases where the licensing authority is required²⁰ to consult that advisory body²¹. However, an advisory body may arrange for an expert advisory group to provide advice or assistance in relation to the performance of any of the excepted functions²².

The Commission on Human Medicines must establish the following expert advisory groups:

- 27 (1) the biologicals expert advisory group, to advise on the safety, quality and efficacy of medicinal products²³ of biological or bio-technological origin, including vaccines²⁴;
- 28 (2) the chemistry, pharmacy and standards expert advisory group, to advise on the quality, and quality in relation to safety and efficacy, of medicinal products which are the subject of an application for a product licence²⁵ under the Medicines Act 1968, a marketing authorisation²⁶ under the marketing authorisation regulations, a certificate of registration²⁷ under the homoeopathic regulations, a traditional herbal registration²⁸ under the herbal regulations or a request for authorisation²⁹ under the clinical trials regulations³⁰;
- 29 (3) the pharmacovigilance expert advisory group, to advise on pharmacovigilance and other issues relating to the safety of medicinal products³¹;
- 30 (4) such others as it considers appropriate³².

1 For the meaning of 'advisory body' see PARA 13 note 8 ante.

2 As to the Secretary of State see PARA 3 note 3 ante.

3 Medicines Act 1968 s 5(1), Sch 1A para 3(1) (s 5(1) amended, and Sch 1A added, by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, regs 6(1), (2), 7). 'Expert advisory group' means an expert advisory group established under the Medicines Act 1968 Sch 1A para 3 (as added) or Sch 1A para 4 (as added) (see the text and notes 21-31 *infra*): s 132(1) (definition added by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 8, Sch 1 para 14(c)).

4 Medicines Act 1968 Sch 1A para 3(2) (as added: see note 3 *supra*).

5 *Ibid* Sch 1A para 3(3) (as added: see note 3 *supra*).

6 In the case of the expert advisory groups specified in *ibid* Sch 1A para 4(1)(a)-(c) (as added) (see heads (1)-(3) in the text), the chairmen are appointed by the ministers: see Sch 1A para 4(2) (as added: see note 3 *supra*). For the meaning of 'the ministers' see PARA 3 note 3 *ante*. See also note 12 *infra*.

7 *Ibid* Sch 1A para 3(4) (as added: see note 3 *supra*).

8 *Ibid* Sch 1A para 3(5) (as added: see note 3 *supra*).

9 *Ibid* Sch 1A para 3(6) (as added: see note 3 *supra*).

10 As to the making of regulations see PARA 5 *ante*.

11 A member of an expert advisory group, other than a member of a standing expert advisory group if he is also chairman of that group (see note 12 *infra*), holds and vacates office in accordance with such terms as may be specified in writing upon his appointment by the advisory body or bodies appointing him: Medicines (Advisory Bodies) (Terms of Office of Members) Regulations 2005, SI 2005/2788, reg 5(1), (2). A member's term of office must not exceed four years (reg 5(3)), and a member of an expert advisory group may resign office at any time by notice in writing to the advisory body or bodies which appointed that group (reg 5(4)). 'Standing expert advisory group' means the biologicals expert advisory group, the chemistry, pharmacy and standards expert advisory group, and the pharmacovigilance expert advisory group: reg 1(2); and see also the text to notes 23-31 *infra*. As to the service of notices see PARA 37 note 8 *post*.

The ministers may pay to the members of each expert advisory group such remuneration (if any) and such allowances as may be determined by the ministers with the consent of the Treasury: Medicines Act 1968 Sch 1A para 10 (as added: see note 3 *supra*). As to the Treasury see CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARAS 512-517. As to the defraying of expenses under the Medicines Act 1968 see PARA 11 *ante*.

12 *Ibid* Sch 1A para 6(b) (as added: see note 3 *supra*). A chairman of a standing expert advisory group holds and vacates office as chairman in accordance with the terms of the instrument by which he is appointed and may at any time resign from the office of chairman by notice in writing to the ministers: Medicines (Advisory Bodies) (Terms of Office of Members) Regulations 2005, SI 2005/2788, reg 4(1). The term of office of a chairman of a standing expert advisory group must not exceed four years: reg 4(2). Where a person ceases to be the chairman of a standing expert advisory group, and is not immediately re-appointed as chairman, he ceases to be a member of the Commission on Human Medicines and that group: reg 4(3). As to the Commission on Human Medicines see PARA 13 *et seq ante*. A chairman of an expert advisory group, other than a chairman of a standing expert advisory group, holds and vacates office as chairman in accordance with such terms as may be specified in writing upon his appointment by the advisory body or bodies appointing him (reg 6(1), (2)), and his term of office must not exceed the remainder of his term as a member of the expert advisory group (reg 6(3)). A chairman of an expert advisory group may at any time resign from the office of chairman by notice in writing to the advisory body or bodies which appointed that group: reg 6(4).

13 Medicines Act 1968 Sch 1A para 11 (as added: see note 3 *supra*).

14 *Ibid* Sch 1A para 9(2) (as added: see note 3 *supra*).

15 *Ibid* Sch 1A para 8(a) (as added: see note 3 *supra*).

16 *Ibid* Sch 1A para 8(b) (as added: see note 3 *supra*).

17 *Ibid* Sch 1A para 12 (as added: see note 3 *supra*).

18 *Ibid* Sch 1A para 5(1) (as added: see note 3 *supra*).

19 For the meaning of 'the licensing authority' see PARA 43 note 8 *post*.

20 *Ie* under the Medicines Act 1968 Pt II (ss 6-50) (as amended) (see PARA 44 *et seq post*), the clinical trials regulations, the herbal regulations, the homoeopathic regulations or the marketing authorisation regulations. For the meaning of 'the clinical trials regulations' see PARA 9 note 10 *ante*. For the meaning of 'the marketing

authorisation regulations' see PARA 14 note 5 ante; for the meaning of 'the homoeopathic regulations' see PARA 14 note 7 ante; and for the meaning of 'the herbal regulations' see PARA 14 note 8 ante.

21 Ibid Sch 1A para 5(2) (as added (see note 3 supra); and amended by the Medicines (Advisory Bodies) (No 2) Regulations 2005, SI 2005/2754, reg 2, Sch 1 para 4(b)).

22 Medicines Act 1968 Sch 1A para 5(3) (as added: see note 3 supra).

23 For the meaning of 'medicinal product' see PARA 7 ante.

24 Medicines Act 1968 Sch 1A para 4(1)(a) (as added: see note 3 supra). As to the appointment of the chairman of such a group see note 6 supra.

25 For the meaning of 'product licence' see PARA 44 note 5 post.

26 As to marketing authorisations see PARA 18 et seq post.

27 See PARA 205 post.

28 See PARA 230 post.

29 Ie pursuant to the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 17: see PARA 95 post.

30 Medicines Act 1968 Sch 1A para 4(1)(b) (as added (see note 3 supra); and amended by the Medicines (Advisory Bodies) (No 2) Regulations 2005, SI 2005/2754, Sch 1 para 4(a)). As to the appointment of the chairman of such a group see note 6 supra.

31 Medicines Act 1968 Sch 1A para 4(1)(c) (as added: see note 3 supra). As to the appointment of the chairman of such a group see note 6 supra.

32 Ibid Sch 1A para 4(1)(d) (as added: see note 3 supra).

UPDATE

17 Expert advisory groups

NOTE 12--Medicines Act 1968 Sch 1A para 6 renumbered as para 6(1); regulations made under Sch 1A para 6(1) may include such incidental, supplemental, consequential or transitional provision as appears to the ministers to be expedient: Sch 1A para 6(2) (Sch 1A para 6 amended by the Health Act 2009 Sch 3 para 1).

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(3) MARKETING AUTHORISATIONS

(i) In general

18. Introduction.

A medicinal product, whether for human use or a veterinary medicinal product, may not generally be placed on the market without a marketing authorisation¹. A parallel system operates in relation to the grant of authorisations. There is a centralised system operating at the level of the European Union under which a single authorisation valid throughout the European Union is issued by the European Commission²; and there are national systems whereby authorisations valid only in individual states are issued by national authorities³. These national systems are based on European Union legislation aimed at removing barriers to trade in medicinal products and the adoption of standard procedures throughout the European Union⁴.

1 See PARAS 19-20 post. In relation to products for human use see also PARA 20 post; and in relation to veterinary medicinal products see also PARA 34 post.

2 I.e. the system operating under EC Council Regulation 2309/93 (OJ L214, 24.8.1993, p 1) (as amended): see PARA 19 post.

3 See the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144 (as amended) (see PARAS 20-33 post); and the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142 (as amended) (see PARAS 34-39 post).

4 I.e. EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) on the Community code relating to medicinal products for human use (as amended), which is implemented in the United Kingdom by the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144 (as amended) (see note 3 supra); and EC Parliament and Council Directive 2001/82 (OJ L311, 28.11.2001, p 1) on the Community code relating to veterinary medicinal products, which is implemented by the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142 (as amended) (see note 3 supra).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(3) MARKETING AUTHORISATIONS/(ii) Community Marketing Authorisations/19. Community marketing authorisations.

(ii) Community Marketing Authorisations

19. Community marketing authorisations.

European Union legislation¹ establishes a centralised community authorisation procedure in respect of the placing on the market of medicinal products which are intended for use in human beings or in food-producing animals², under which a marketing authorisation valid throughout the European Union can be issued by the European Commission. The European Agency for the Evaluation of Medicinal Products is established to provide the Commission with objective scientific advice on products in respect of which applications for authorisations are made³.

Certain medicinal products for human use may not be placed on the market within the European Union without a marketing authorisation⁴, and in respect of certain other such products the person placing the product on the market may request the issue of a marketing authorisation⁵. An application for an authorisation must be submitted to the European Agency for the Evaluation of Medicinal Products⁶. Where a marketing authorisation is granted it is valid throughout the European Union⁷, and the refusal of an authorisation is a prohibition on placing the product concerned on the market throughout the European Union⁸. There are provisions for the supervision of products once they are authorised⁹ and for the reporting of adverse reactions to marketed products¹⁰.

There are similar provisions relating to the placing on the market of veterinary products for food-producing animals¹¹.

1 I.e. EC Council Regulation 2309/93 (OJ L214, 24.8.1993, p 1) laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products (amended by EC Commission Regulation 649/98 (OJ L88, 24.3.1998, p 7); EC Council Regulation 807/2003 (OJ L122, 16.5.2003, p 36); and EC Council Regulation 1647/2003 (OJ L245, 29.9.2003, p 19)). The legislation, being by way of a regulation, has direct effect in member states without the need for further national legislation. As to the principle of direct effect see CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARA 24.

2 See EC Council Regulation 2309/93 (OJ L214, 24.8.1993, p 1) preamble.

3 See *ibid* Title IV (arts 49-66).

4 See *ibid* art 3(1), Annex Pt A.

5 See *ibid* art 3(2), Annex Pt B.

6 See *ibid* art 4. As to the content of applications see art 6. As to the determination of applications see arts 7-11, 67-68.

7 See *ibid* art 12(1). Authorisations are valid for five years and are renewable for five year periods: see art 13(1).

8 See *ibid* art 12(2).

9 See *ibid* Ch 2 (arts 15-18).

10 See *ibid* Ch 3 (arts 19-26).

11 See *ibid* Title III (arts 27-48).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(3) MARKETING AUTHORISATIONS/(iii) Medicines for Human Use/20. United Kingdom marketing authorisations.

(iii) Medicines for Human Use

20. United Kingdom marketing authorisations.

Subject to certain exceptions and exemptions¹, no relevant medicinal product² may be placed on the market³, and no such product may be distributed by way of wholesale dealing⁴, unless a marketing authorisation⁵ in respect of that product has been granted in accordance with the relevant Community provisions by the licensing authority or the European Commission, and is for the time being in force⁶. These prohibitions do not apply to:

- 31 (1) a relevant medicinal product supplied in response to a bona fide unsolicited order, formulated in accordance with the specification of a doctor⁷, dentist⁸ or supplementary prescriber⁹ and for use by his individual patients on his direct personal responsibility in order to fulfil the special needs of those patients¹⁰;
- 32 (2) anything done:
 - 1
 - 1. (a) by a doctor or dentist which relates to a relevant medicinal product specially prepared by him, or to his order, for administration¹¹ to one or more patients of his or, where that doctor or dentist is a member of a group of doctors or dentists working together to provide primary medical services or general dental services, to one or more patients of any other doctor or dentist of that group, and which consists of procuring the manufacture¹² or assembly¹³ of a stock of the product with a view to administering the product to such patients¹⁴; or
 - 2. (b) in a registered pharmacy¹⁵, hospital¹⁶ or health centre¹⁷, which is done there by or under the supervision of a pharmacist¹⁸, and consists of procuring the manufacture or assembly of a stock of relevant medicinal products with a view to dispensing them in accordance with head (1) above¹⁹;
 - 2
 - 33 (3) the placing on the market by way of supplying of any relevant medicinal product which is for use by being administered to one or more human beings and which may be lawfully sold by retail²⁰ or supplied in circumstances corresponding to retail sale, otherwise than in accordance with a prescription by a doctor or dentist²¹;
 - 34 (4) certain radiopharmaceuticals for human use²²;
 - 35 (5) a medicinal product for which there is in force an authorisation to place the product on the market granted by the licensing authority in accordance with the Directive²³ on the Community code relating to medicinal products for human use²⁴.

Any person who sells or supplies a relevant medicinal product in accordance with any of heads (1) to (3) above must maintain, and keep for a period of at least five years, certain records²⁵.

Where, in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation which may cause harm to humans, the licensing authority recommends or requires the use of a medicinal product which is not the subject of a Community marketing authorisation or a United Kingdom marketing authorisation²⁶, or a medicinal product which is the subject of such an authorisation for a therapeutic indication which is not included in the summary of product characteristics under that authorisation²⁷, the holder of the authorisation for the product in question, a manufacturer of that product, an officer, servant, employee or agent of the licence holder or manufacturer, and health

professionals, are not subject to any civil liability for any loss or damage resulting from the use of the product in accordance with the recommendation or requirement²⁸.

1 le those set out in the relevant Community provisions and in the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 1 paras 1, 3-5A (see the text to notes 7-24 infra); reg 3(1). 'The relevant Community provisions' means the provisions of EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) on the Community code relating to medicinal products for human use (amended by EC Parliament and Council Directive 2002/98 (OJ L33, 8.2.2003, p 30); EC Commission Directive 2003/63 (OJ L159, 27.6.2003, p 46); EC Parliament and Council Directive 2004/24 (OJ L136, 30.4.2004, p 85); EC Parliament and Council Directive 2004/27 (OJ L136, 30.4.2004, p 34)); EC Commission Regulation 540/95 (OJ L55, 11.3.1995, p 5); EC Parliament and Council Regulation 141/2000 (OJ L18, 22.1.2000, p 1); EC Commission Regulation No 847/2000 (OJ L103, 28.4.2000, p 5); EC Commission Regulation 1084/2003 (OJ L159, 27.6.2003, p 1); EC Commission Regulation 1085/2003 (OJ L159, 27.6.2003, p 24); and EC Parliament and Council Regulation 726/2004 (OJ L137, 30.4.2004, p 1); Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 1(2) (amended by SI 2002/236; SI 2003/2321; SI 2004/3224; SI 2005/50; SI 2005/2759). For these purposes, 'the Community' means the European Community: Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 1(2).

In so far as they relate to relevant medicinal products and fall to be performed by, or by any authority of, the United Kingdom, the functions of a member state, or of the competent authority of a member state, under any of the relevant Community provisions are performed by the licensing authority: reg 2(1). However, this does not apply in so far as any such functions fall to be performed by the exercise of any powers or duties which are conferred by any provision of the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144 (as amended) or by any provision of the Medicines Act 1968 as applied by the regulations, on a person or body other than the licensing authority: reg 2(2). For the meaning of 'United Kingdom' see PARA 7 note 3 ante. For the meaning of 'member state' see the European Communities Act 1972 s 1(2), Sch 1 Pt II; and the Interpretation Act 1978 s 5, Sch 1. For the meaning of 'the licensing authority' see PARA 43 note 8 post.

2 'Relevant medicinal product' means, except in the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 3A (as added) (see PARA 21 post) and Sch 3 para 1A (as added) (see PARA 30 post), a medicinal product for human use to which the provisions of EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) (as amended) apply, other than a traditional herbal medicinal product or a homoeopathic medicinal product that fulfils the conditions laid down in art 14(1): Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 1(2) (definition substituted by SI 2005/2759). 'Traditional herbal registration' means a traditional herbal registration granted by the licensing authority under the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, SI 2005/2750 (see PARA 230 post): Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 1(2) (definition added by SI 2005/2759).

For cases relating to the classification of medicinal products see: Case C-227/82 *Van Bennekom* [1983] ECR 3883, [1985] 2 CMLR 692, ECJ; Case C-35/85 *Procureur de la Republique v Tissier* [1986] ECR 1207, [1987] 1 CMLR 551, ECJ; Case C-60/89 *Re Monteil and Samanni* [1991] ECR I-1547, [1992] 3 CMLR 425, 14 BMLR 112, ECJ; Case C-112/89 *Upjohn Co and Upjohn NV v Farzoo Inc and Kortmann* [1991] ECR I-1703, [1993] 1 CMLR 657, 14 BMLR 79, ECJ; Case C-290/90 *EC Commission v Germany* [1992] ECR I-3317, ECJ; Case C-219/91 *Re Ter Voort* [1992] ECR I-5485, [1995] 2 CMLR 591, 30 BMLR 165, ECJ; *R v Medicines Control Agency, ex p Pharma Nord (UK) Ltd* [1998] 3 CMLR 109, 44 BMLR 41, CA; Case C-94/98 *R v Medicines Control Agency, ex p Rhone-Poulenc Rorer Ltd* [2000] All ER (EC) 46, ECJ; Joined Cases C-211/03, C-299/03 and C-316/03-C-318/03 *HLH Warenvertriebs GmbH v Germany* [2005] All ER (D) 56 (Jun), ECJ.

3 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 3(1)(a).

4 Ibid reg 3(1)(b). For the meaning of 'wholesale dealing' see PARA 47 note 5 post.

5 Except where the contrary intention appears, any reference to a marketing authorisation includes a reference both to a United Kingdom marketing authorisation (including a product licence having effect as such an authorisation) and to a Community marketing authorisation: ibid reg 1(4)(a). For the meaning of 'product licence' see PARA 44 note 5 post. 'United Kingdom marketing authorisation' means a marketing authorisation granted by the licensing authority under the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144 (as amended), and includes a parallel import licence: reg 1(2) (definition substituted by SI 2001/795). 'Parallel import licence' means a United Kingdom marketing authorisation granted by the licensing authority in respect of a relevant medicinal product which is imported into the United Kingdom from another EEA state in accordance with the rules of Community law relating to parallel imports: Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 1(2) (definition added by SI 2001/795). 'EEA state' means a member state, Norway, Iceland or Liechtenstein: Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 1(2) (definition added by SI 2001/795; and amended by SI 2005/2759). 'Community marketing authorisation' means a marketing authorisation granted by the European Commission under EC Council Regulation 2309/93 (OJ L214, 24.8.1993, p 1) or EC Parliament and

Council Regulation 726/2004 (OJ L136, 30.4.2004, p 1): Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 1(2) (definition amended by SI 2005/2759).

6 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 3(1). The Medicines Act 1968 s 7 (dealing with medicinal products and product licences: see PARA 44 post) does not apply in relation to relevant medicinal products: Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 9(2). As to offences relating to marketing authorisations see PARA 30 post. The Medicines Act 1968 s 3 (see PARA 14 ante), s 4 (see PARA 15 ante), s 23 (see PARA 66 post), s 58A (as added) (see PARA 141 post), s 59 (see PARA 142 post), s 92 (see PARA 157 post), s 103 (see PARA 151 post), and the Medicines Act 1971 s 1 (see PARA 11 ante) apply to the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144 (as amended) with certain modifications: see reg 9(1), (3)-(10), (12), (15) (16) (reg 9(15), (16) added by SI 2005/2759). The provisions of the Trade Descriptions Act 1968 apply to the application of a trade description to goods subject to a marketing authorisation in the same way as, by virtue of s 2(5)(b) (see SALE OF GOODS AND SUPPLY OF SERVICES vol 41 (2005 Reissue) PARA 482), they apply to the application of a trade description to goods subject to any provision made under the Medicines Act 1968 Pt V (ss 85-91) (as amended) (see PARAS 152-156 post): Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 9(11). The consumer safety provisions of the Consumer Protection Act 1987 Pt II (ss 10-19) (as amended) (see SALE OF GOODS AND SUPPLY OF SERVICES vol 41 (2005 Reissue) PARA 528 et seq) apply to a relevant medicinal product in respect of which a United Kingdom marketing authorisation or a Community marketing authorisation is for the time being in force: see the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 9(13).

7 For the meaning of 'doctor' see PARA 7 note 10 ante.

8 For the meaning of 'dentist' see PARA 7 note 10 ante.

9 'Supplementary prescriber' means: (1) a first level nurse; (2) a pharmacist; (3) a registered midwife; (4) a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of the Health Professions Order 2001, SI 2002/254, art 5 (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 325) relating to chiropodists and podiatrists, physiotherapists, radiographers (diagnostic or therapeutic), or against whose name is recorded, in the relevant register, an annotation or entry signifying that he is qualified to order drugs, medicines and appliances as a supplementary prescriber; or (5) a registered optometrist: Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 1(2) (amended by SI 2005/1250). 'Relevant register' means: (a) in relation to a first level nurse or registered midwife, the professional register; (b) in relation to a pharmacist, the register maintained in pursuance of the Pharmacy Act 1954 s 2(1) (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 888); (c) in relation to a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of the Health Professions Order 2001, SI 2002/254, art 5 relating to chiropodists and podiatrists, physiotherapists, radiographers (diagnostic or therapeutic), that register; and (d) in relation to a registered optometrist, the register of optometrists maintained under the Opticians Act 1989 s 7(a) (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 838): Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 1(2) (definitions added by SI 2005/768; and amended by SI 2005/1520). 'First level nurse' means a person registered in Sub-Part 1 of the Nurses' Part of the professional register; 'registered midwife' means a person registered in the Midwives' Part of the professional register; and 'professional register' means the register maintained by the Nursing and Midwifery Council under the Nursing and Midwifery Order 2001, SI 2002/253, art 5 (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 717): Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 1(2) (definitions added by SI 2005/768). 'Registered optometrist' means a person whose name is entered in the register of optometrists maintained under the Opticians Act 1989 s 7(a): Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 1(2) (definition added by SI 2005/1520). For the meaning of 'pharmacist' for the purposes of the Medicines Act 1968 see PARA 46 note 10 post.

10 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 3(2), Sch 1 para 1 (amended by SI 2005/2759). Such supply is subject to certain conditions: Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 1 para 1 (as so amended). As to the conditions see Sch 1 para 2 (amended by SI 2004/1031; SI 2005/768; SI 2005/2759).

11 As to the meaning of 'administer' see PARA 7 note 2 ante.

12 As to the meaning of 'manufacture' see PARA 7 note 2 ante.

13 For the meaning of 'assembly' see PARA 6 note 8 ante.

14 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 1 para 3(1) (a) (amended by SI 2004/865; SI 2004/1016). As to primary medical services and general dental services see HEALTH SERVICES vol 54 (2008) PARA 241 et seq.

The exemption conferred by the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 1 para 3(1) (as amended) does not apply to procuring the manufacture of relevant medicinal

products unless those products are to be manufactured by the holder of a manufacturer's licence which relates specifically to the manufacture or assembly of relevant medicinal products to which that provision applies: Sch 1 para 3(2). For the meaning of 'manufacturers licence' see PARA 46 note 7 post. Nor does the exemption apply to anything done by a doctor or dentist in relation to a stock held by him of such relevant medicinal products in excess of a total of five litres of fluid and 2.5 kilograms of solids of all such relevant medicinal products: Sch 1 para 3(3).

15 For the meaning of 'registered pharmacy' see PARA 51 note 3 post.

16 As to the meaning of 'hospital' see PARA 7 note 9 ante.

17 For the meaning of 'health centre' see PARA 51 note 9 post.

18 For the meaning of 'pharmacist' see PARA 46 note 10 post.

19 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 1 para 3(1) (b). See note 14 supra.

20 As to references to selling by retail see PARA 7 note 12 ante.

21 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 1 para 4(1), (2). To qualify under this exemption certain conditions must be satisfied: Sch 1 para 4(1). As to the conditions see Sch 1 para 4(3). As to products on a general sale list see PARA 133 et seq post; and as to prescription only medicinal products see PARA 140 et seq post.

22 See *ibid* Sch 1 para 5(1). To qualify under this exemption certain conditions must be met: Sch 1 para 5(1). As to the conditions see Sch 1 para 5(1)(a)-(c). 'Radiopharmaceutical' means any relevant medicinal product which when ready for use contains one or more radionuclides included for a medicinal purpose: Sch 1 para 5(2).

23 *Ie* EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 126a.

24 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 1 para 5A (added by SI 2005/2759).

25 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 1 para 6. The records must show: (1) the source from which that person obtained that product (Sch 1 para 6(a)); (2) the person to whom and the date on which the sale or supply was made (Sch 1 para 6(b)); (3) the quantity of each sale or supply (Sch 1 para 6(c)); (4) the batch number of the batch of that product from which the sale or supply was made (Sch 1 para 6(d)); and (5) details of any suspected adverse reaction to the product so sold or supplied of which he is aware (Sch 1 para 6(e)). A person required to maintain such records must: (a) notify the licensing authority of any suspected adverse reaction such as is mentioned in head (5) supra which is a serious adverse reaction (Sch 1 para 7(a)); and (b) make available for inspection at all reasonable times by the licensing authority all such records (Sch 1 para 7(b)). It is an offence to fail to maintain records, to fail to make them available for inspection or to give notification as required: see PARA 30 post.

26 *Ibid* reg 3B(1)(a) (reg 3B added by SI 2005/2759).

27 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 3B(1)(b) (as added: see note 26 supra).

28 See *ibid* reg 3B(2)-(4) (as added: see note 26 supra).

UPDATE

20 United Kingdom marketing authorisations

NOTE 1--SI 1994/3144 reg 1(2) further amended: SI 2006/1952, SI 2008/3097.

Directive 2001/83: further amended by European Parliament and EC Council Regulations 1901/2006 (OJ L378, 27.12.2006, p 1), 1394/2007 (OJ L324, 10.12.2007, p 121) and European Parliament and EC Council Directive 2008/29 (OJ L81, 20.3.2008, p 51).

NOTE 2--See also Case C-387/99 *Re Vitamin Supplements: EC Commission v Germany* [2006] 3 CMLR 491, ECJ.

NOTE 5--In SI 2004/1031 reg 2(1) definition of 'EEA state' replaced in identical terms by SI 2006/1928.

NOTE 9--In the definition of 'supplementary prescriber' in head (1), for 'first level nurse' read 'registered nurse' and in head (4), after the words 'supplementary prescriber' add 'or, in the case of a nurse or midwife, as a nurse independent/supplementary prescriber': SI 1994/3144 reg 1(2) (definition amended by SI 2006/914). 'Registered nurse' means a person registered in the Nurses' Part or Specialist Community Public Health Nurses' Part of the professional register: SI 1994/3144 reg 1(2) (definition added by SI 2006/914). In the definition of 'relevant register' in head (a) for 'first level nurse' read 'registered nurse': SI 1994/3144 reg 1(2) (definition amended by SI 2006/914). Definition of 'relevant register' further amended: SI 2007/289.

NOTE 10--SI 1994/3144 Sch 1 paras 1, 2 further amended: SI 2009/3063.

TEXT AND NOTE 14--For 'general dental services' read 'primary dental services': SI 1994/3144 Sch 1 para 3(1)(a) (amended by SI 2006/562).

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21. Borderline products.

Where the licensing authority¹ is of the opinion that a product without a marketing authorisation², traditional herbal registration³ or certificate of registration⁴ is a relevant medicinal product⁵, it may, by a notice in writing⁶ (a 'provisional determination notice') served on any person⁷ who has placed or who in the opinion of the licensing authority may place the product on the market: (1) inform him that it is minded to determine that the product is a relevant medicinal product ('the provisional determination') and of the reasons why it is so minded⁸; and (2) advise him that if he disagrees with the provisional determination, he may request that the licensing authority review the provisional determination⁹. Where a person on whom a provisional determination notice has been served has not requested that the licensing authority review its provisional determination within four weeks of the date of the provisional determination¹⁰, or has made such a request but has not availed himself of the opportunities afforded to him under the procedure¹¹ to make representations explaining why he considers that the product in respect of which the provisional determination has been made is not a relevant medicinal product¹², the licensing authority must, after further consideration of the matter, determine whether or not the product is a relevant medicinal product and inform that person in writing of its determination and the reasons for it¹³.

Where the licensing authority has been informed¹⁴ that a person wishes to make oral representations to a review panel, it must, after consultation with that person, set a date for the oral hearing¹⁵.

If a person on whom a provisional determination notice was served has made written representations to the licensing authority, the licensing authority must put those written representations before a review panel, appointed by the licensing authority, together with any written representations which the licensing authority may make to the panel on the matter¹⁶, and, after further consideration of the matter and in particular after having considered the advice of the review panel arising out of those representations and any other evidence considered by the review panel¹⁷, determine whether or not the product is a relevant medicinal product¹⁸. If a person on whom a provisional determination notice was served has made oral representations to a review panel at an oral hearing, the licensing authority must, after further consideration of the matter and, in particular after having considered the advice of the review panel arising out of the oral representations made and any other evidence submitted to the panel at the hearing by that person¹⁹, any oral representations made and any other evidence submitted to the panel at the hearing by the licensing authority²⁰, and any other evidence considered by the review panel²¹, determine whether or not the product is a relevant medicinal product²². In either case, the licensing authority must inform the person in writing of its determination and the reasons for it, and if the licensing authority makes a determination which is contrary to the advice of the review panel, it must also give the reasons for disagreeing with that advice²³. In respect of any product which the licensing authority determines to be a relevant medicinal product, it may, by a notice in writing served on any person who has placed or who in its opinion may place the product on the market, require that he must stop marketing the product from a date specified in the notice²⁴, or not place the product on the market²⁵, unless or until a marketing authorisation, traditional herbal registration or certificate of registration is granted in respect of that product²⁶.

Nothing in these provisions precludes a determination by the licensing authority that a product is a relevant medicinal product otherwise than in accordance with these provisions in appropriate circumstances²⁷.

1 For the meaning of 'the licensing authority' see PARA 43 note 8 post.

2 As to the meaning of 'marketing authorisation' see PARA 20 note 5 ante.

3 For the meaning of 'traditional herbal registration' see PARA 20 note 2 ante.

4 'Certificate of registration' means a certificate of registration granted by the licensing authority under the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105 (see PARA 205 post): Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 1(2) (definition added by SI 2005/2759).

5 In the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 3A (as added), 'relevant medicinal product' means a medicinal product for human use to which the provisions of EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) (as amended) apply: Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 3A(8) (added by SI 2005/2759).

6 'Writing' includes any form of notation, whether by hand or by printing, typewriting or any similar process; and 'written' has a corresponding meaning: Medicines Act 1968 s 132(1); Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 1(6).

7 'Person' includes a body of persons corporate or unincorporate: Interpretation Act 1978 s 5, Sch 1. As to bodies corporate and unincorporate see COMPANIES; CORPORATIONS.

8 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 3A(1)(a) (reg 3A added by SI 2000/292).

9 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 3A(1)(b) (as added: see note 8 supra). The notice must also advise him that he must make the request within four weeks of the date on which the provisional determination notice was served on him ('the date of the provisional determination') (see reg 3A(1)(b) (as so added)), and that he must: (1) within such period (being not less than six weeks from the date of the provisional determination) as may be specified in the notice, furnish the licensing authority with written representations explaining why he considers that the product is not a relevant medicinal product (reg 3A(1)(b)(i) (as so added)); or (2) within four weeks of the date of the provisional determination, inform the licensing authority in writing that he wishes to make oral representations to a review panel, appointed by the licensing authority, explaining why he considers that the product is not a relevant medicinal product (reg 3A(1)(b)(ii) (as so added)).

10 Ibid reg 3A(4)(a) (as added: see note 8 supra).

11 See note 9 supra.

12 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 3A(4)(b) (as added: see note 8 supra).

13 Ibid reg 3A(4) (as added: see note 8 supra).

14 Ie pursuant to ibid reg 3A(1)(b)(ii) (as added): see note 9 supra.

15 Ibid reg 3A(2) (as added: see note 8 supra). Subject to reg 3A(3) (as added), that date is the date fixed for the oral hearing. The licensing authority may also make oral representations to the panel: reg 3A(2) (as so added). Where the licensing authority considers that, because of either exceptional circumstances or the nature and complexity of the issues, additional time is needed:

- 12 (1) for the preparation of written representations in a case where the licensing authority has not been informed that the person on whom the provisional determination notice was served wishes to make oral representations, the licensing authority may alter the period specified in the notice within which written representations are to be furnished to a different period, and then that different period is the period within which the written representations are to be furnished (reg 3A(3)(a) (as so added));

- 13 (2) for preparation for the oral hearing, it may alter the date set for the hearing to a different date, and then that different date is the date fixed for the oral hearing (reg 3A(3)(b) (as so added)),

and it must inform the person on whom the relevant provisional determination notice was served of the alteration and the reasons for it (reg 3A(3) (as so added)).

16 Ibid reg 3A(5)(a)(i) (as added: see note 8 supra).

17 Ibid reg 3A(5)(a)(ii) (as added: see note 8 supra).

18 Ibid reg 3A(5)(a) (as added: see note 8 supra).

19 Ibid reg 3A(5)(b)(i) (as added: see note 8 supra).

20 Ibid reg 3A(5)(b)(ii) (as added: see note 8 supra).

21 Ibid reg 3A(5)(b)(iii) (as added: see note 8 supra).

22 Ibid reg 3A(5)(b) (as added: see note 8 supra).

23 Ibid reg 3A(5) (as added: see note 8 supra).

24 Ibid reg 3A(6)(a) (as added: see note 8 supra).

25 Ibid reg 3A(6)(b) (as added: see note 8 supra).

26 Ibid reg 3A(6) (as added (see note 8 supra); amended by SI 2005/2759). It is an offence to fail to comply with such a notice: see PARA 30 post.

27 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144 reg 3A(7) (as added: see note 8 supra).

UPDATE

21 Borderline products

TEXT AND NOTES 1-9--The use of the word 'may' indicates that SI 1994/3144 reg 3A is not the sole mandatory machinery for determining whether a product is a relevant medicinal product: *R v Wright* [2007] EWCA Crim 1744, [2007] All ER (D) 315 (Jul).

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22. Applications for the grant, renewal or variation of a United Kingdom marketing authorisation.

Every application for the grant, renewal or variation¹ of a United Kingdom marketing authorisation² for a relevant medicinal product³ must be made in accordance with the relevant Community provisions⁴, subject to the rules of Community law relating to parallel imports, and the applicant must comply with so much of the relevant Community provisions as impose obligations on applicants as are applicable to the application or the consideration of it⁵. Every application must be made in writing⁶, must be signed by or on behalf of the applicant and must, unless the licensing authority⁷ otherwise directs, be accompanied by any fee which may be payable in connection with that application⁸. The applicant for the grant or renewal of a United Kingdom marketing authorisation must be established in the Community⁹.

One copy of the application and of any accompanying material must be supplied to the licensing authority in the English language and where the application or any accompanying material has been translated from another language, one copy of the application or the accompanying material, as the case may be, must also be supplied in the original language¹⁰. An application for the grant of a marketing authorisation must include a statement indicating whether the relevant medicinal product is one that should be available only on prescription¹¹, only from a pharmacy¹², or on general sale¹³, and what, if any, provisions of the authorisation are proposed concerning the method of sale or supply of the product (including, in particular, any proposed restrictions affecting the circumstances of the use or promotion of the product)¹⁴.

An application for the renewal of a marketing authorisation must be made not later than six months¹⁵ before the date on which the existing authorisation expires¹⁶.

1 Except where the contrary intention appears: (1) any reference to the variation of a marketing authorisation includes a reference to a change in the requirements for labels or package leaflets (Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 1(4)(b)); (2) any reference to an application for the variation of a marketing authorisation includes a reference to a notification of such a variation, and any reference to an applicant for a variation to a marketing authorisation includes a reference to a person submitting such a notification (reg 1(4)(bb) (added by SI 2003/2321)); and (3) any reference to an application for the grant or renewal of a marketing authorisation is a reference to an application made after 1 January 1995 (Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 1(1), (4)(c)).

2 For the meaning of 'United Kingdom marketing authorisation' see PARA 20 note 5 ante.

3 For the meaning of 'relevant medicinal product' see PARA 20 note 2 ante.

4 For the meaning of 'the relevant Community provisions' see PARA 20 note 1 ante.

5 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 4(1) (amended by SI 2001/795). For the purposes of EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 10, the period of eight years there mentioned (ie the period during which reference medicinal products must have been authorised) does not apply if the application for the authorisation of the reference medicinal product was submitted before 30 October 2005: Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 4(6) (reg 4(6) substituted, and reg 4(6A), (6B) added, by SI 2005/2759). Where, by reason of the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 4(6), the period of eight years does not apply, the applicant is not required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which has been authorised in an EEA state for not less than ten years: reg 4(6A) (as so added). EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 10(1) fourth

sub-paragraph does not apply if the application for the initial authorisation of the reference medicinal product was submitted before 30 October 2005 (Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 4(6B) (as so added)); and an applicant is not entitled by virtue of EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 10.1(a) to omit to provide any particulars or results if proper consideration of the application without them could not be carried out without prejudicing any rights which arise under any law relating to the protection of industrial and commercial property and which are enforceable in the United Kingdom: Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 4(7) (amended by SI 2002/236). For the meaning of 'EEA state' see PARA 20 note 5 ante. For the meaning of 'United Kingdom' see PARA 7 note 3 ante. As to what constitutes an essentially similar product and the grant of marketing authorisations in respect thereof see Case C-368/96 *R v Licensing Authority established by the Medicines Act 1968, ex p Generics (UK) Ltd (ER Squibb & Sons Ltd, intervener)* (1999) 48 BMLR 161, ECJ; Case C-106/01 *R (on the application of Novartis Pharmaceuticals UK Ltd) v Licensing Authority* [2005] All ER (EC) 192, (2004) 81 BMLR 200, ECJ; *R (on the application of Merck Sharp & Dohme Ltd) v Licensing Authority* [2005] EWHC 710 (Admin), [2005] All ER (D) 401 (Apr). As to applications relating to parallel imports see Case C-94/98 *R v Medicines Control Agency, ex p Rhone-Poulenc Rorer Ltd* [2000] All ER (EC) 46, ECJ.

6 For the meaning of 'writing' see PARA 21 note 6 ante.

7 For the meaning of 'the licensing authority' see PARA 43 note 8 post.

8 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 4(2). As to fees see the Medicines (Products for Human Use--Fees) Regulations 1995, SI 1995/1116 (amended by SI 1996/683; SI 1998/574; SI 1999/566; SI 2000/592; SI 2000/3031; SI 2001/795; SI 2002/236; SI 2002/542; SI 2003/625; SI 2003/2321; SI 2004/666; SI 2004/1157; SI 2005/1124).

9 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 4(8). For the meaning of 'the Community' see PARA 20 note 1 ante.

10 Ibid reg 4(3) (substituted by SI 2005/2759).

11 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 4(5)(a)(i). As to prescription only medicinal products see PARA 140 et seq post.

12 Ibid reg 4(5)(a)(ii).

13 Ibid reg 4(5)(a)(iii). As to general sale lists see PARA 133 et seq post.

14 Ibid reg 4(5)(b).

15 'Month' means calendar month: Interpretation Act 1978 s 5, Sch 1.

16 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 4(9) (amended by SI 2005/2759).

UPDATE

22 Applications for the grant, renewal or variation of a United Kingdom marketing authorisation

TEXT AND NOTE 5--Subject also to the rules of Community law relating to national homoeopathic products: SI 1994/3144 reg 4(1) (amended by SI 2006/1952). As to an application for a grant of marketing authorisation for a national homoeopathic product, see SI 1994/3144 reg 4(1A)-(1C), Sch 1A (added by SI 2006/1952).

NOTE 5--A medicinal product, in order that it may be considered to be a reference medicinal product, must have been authorised in accordance with Community law before being placed on the market: Case C-527/07 *R (on the application Generics (UK) Ltd) v Licensing Authority* (2009) 111 BMLR 46, ECJ.

NOTE 8--SI 1995/1116 now replaced by Medicines (Products for Human Use) (Fees) Regulations 2009, SI 2009/389 (amended by SI 2009/3222).

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23. Consideration, and grant or refusal, of applications.

The licensing authority¹ must consider every application for the grant, renewal or variation by it of a marketing authorisation² in accordance with the relevant Community provisions³ and where applicable the rules of Community⁴ law relating to parallel imports, and must grant, renew or vary, or refuse to grant, renew or vary, the authorisation in accordance with those provisions and, where applicable, those rules⁵. Each marketing authorisation⁶ granted by the licensing authority on or after 1 April 2002 must be granted subject to a condition that the medicinal product to which the authorisation relates is to be available only on prescription⁷, only from a pharmacy⁸, or on general sale⁹. Where prior to 1 April 2002 a medicinal product was subject to a marketing authorisation and that authorisation contains a statement that it is to be available on one or more of the following bases, namely, only on prescription¹⁰, only from a pharmacy¹¹, or on general sale¹², then it is a condition of the marketing authorisation from 1 April 2002 that the product is to be available only on that basis or, as the case may be, those bases¹³.

A parallel import licence¹⁴ is, unless previously renewed or revoked, valid for the period specified in it, but where an application to renew it is made¹⁵ it remains in force pending the decision of the licensing authority on that application¹⁶; and an authorisation granted by the licensing authority in accordance with the Directive¹⁷ on the Community code relating to medicinal products for human use is, unless previously revoked, valid for the period specified in it¹⁸.

Subject to the provisions relating to lapse¹⁹, a United Kingdom marketing authorisation other than a parallel import licence is, unless previously revoked, valid for an unlimited period unless it has not been renewed on the basis of a re-evaluation²⁰ by the licensing authority of the risk-benefit balance²¹, or it has been so renewed but the licensing authority considers on justified grounds relating to pharmacovigilance that it should be subject to one additional renewal five years after the date of the first renewal, and it has not yet been subject to that additional renewal²². Where, for such reasons, a United Kingdom marketing authorisation is not valid for an unlimited period, it is, unless previously revoked, valid for a period of five years beginning with the date on which it is granted or was renewed, whichever is the later²³.

1 For the meaning of 'the licensing authority' see PARA 43 note 8 post.

2 As to such applications see PARA 22 ante. As to references to marketing authorisations see PARA 20 note 5 ante.

3 For the meaning of 'the relevant Community provisions' see PARA 20 note 1 ante.

4 For the meaning of 'the Community' see PARA 20 note 1 ante.

5 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 5(1) (amended by SI 2001/795). As to the procedure for receiving advice and representations before granting, renewing or varying, or refusing to grant, renew, or vary, a marketing authorisation or after notification of a decision relating to an application to vary such an authorisation see the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 2 (as substituted); and PARA 26 post. As to provisions relating to labels and leaflets see reg 11, Sch 5 (amended by SI 1998/3105; SI 2000/292; SI 2002/236; SI 2002/542; SI 2003/1618); the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 5A (added by SI 1998/3105); and the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 6 (amended by SI 2004/3224; SI 2005/2759). It is an unjustifiable restriction on the free movement of goods between member states to refuse to issue a marketing authorisation for a medicinal product which is authorised in another member state, unless there are imperative needs,

particularly the protection of public health: Case C-112/02 *Kohlpharma GmbH v Bundesrepublik Deutschland* [2004] 2 CMLR 324, ECJ. See also CUSTOMS AND EXCISE vol 12(2) (2007 Reissue) PARA 19.

6 For these purposes, 'marketing authorisation' includes an authorisation granted by the licensing authority in accordance with EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 126a: Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 5A(1A) (reg 5A added by SI 2002/542; reg 5A(1A) added by SI 2005/2759).

7 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 5A(1)(a) (as added: see note 6 supra). As to prescription only medicinal products see PARA 140 et seq post. It is an offence to fail to comply with a condition to an authorisation: see PARA 30 post.

8 Ibid reg 5A(1)(b) (as added: see note 6 supra). See also note 7 supra.

9 Ibid reg 5A(1)(c) (as added: see note 6 supra). As to general sale lists see PARA 133 et seq post. See also note 7 supra.

10 Ibid reg 5A(2)(a) (as added: see note 6 supra).

11 Ibid reg 5A(2)(b) (as added: see note 6 supra).

12 Ibid reg 5A(2)(c) (as added: see note 6 supra).

13 Ibid reg 5A(2) (as added: see note 6 supra). See also note 7 supra.

14 For the meaning of 'parallel import licence' see PARA 20 note 5 ante.

15 Ie in accordance with the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 4(9) (as amended): see PARA 22 ante.

16 Ibid reg 5(4) (reg 5(4) substituted, and reg 5(5)-(9) added, by SI 2005/2759).

17 Ie EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 126a.

18 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 5(5) (as added: see note 16 supra).

19 A United Kingdom marketing authorisation (other than a parallel import licence) ceases to be valid if at any time after it is granted the medicinal product to which it relates is not placed on the market in the United Kingdom for a period of three consecutive years, unless an exemption is granted in accordance with EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 24(6): Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 5(8) (as added: see note 16 supra). For the purposes of calculating the period of three consecutive years no account must be taken of any period before 30 October 2005: reg 5(9) (as so added). For the meaning of 'United Kingdom marketing authorisation' see PARA 20 note 5 ante.

20 Ie in accordance with, and on the basis of the data set out in, EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 24(2).

21 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 5(6)(a) (as added: see note 16 supra).

22 Ibid reg 5(6)(b) (as added: see note 16 supra).

23 Ibid reg 5(7) (as added: see note 16 supra). However, where an application for its renewal is made in accordance with EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 24 the marketing authorisation remains in force pending the decision of the licensing authority on that application: Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 5(7) (as so added).

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24. Revocation, suspension or variation of marketing authorisations and suspension of the use or marketing of medicinal products.

The licensing authority¹ may and, where appropriate must, subject to and in accordance with the relevant Community provisions², revoke, suspend or vary a marketing authorisation³ for a relevant medicinal product⁴. The licensing authority may and, where appropriate, must, subject to and in accordance with the relevant Community provisions, by notice in writing⁵ to the holder of a marketing authorisation for a relevant medicinal product, forthwith or from a date specified in the notice, suspend the use, supply or marketing within the United Kingdom⁶ of the product to which the authorisation relates for a period specified in the notice⁷. Where⁸ the licensing authority or the European Commission revokes or suspends a marketing authorisation, or where the licensing authority suspends the use, supply or marketing of a product, or where the relevant Community provisions so permit or require, the licensing authority may and, where appropriate, must give written notice to the person who is or, immediately before its revocation or suspension, was the holder of the authorisation, requiring him to take all reasonably practicable steps to: (1) inform wholesalers, retailers, medical practitioners, patients and others who may be in possession of relevant products of the revocation or suspension, the reasons for it, and the action, if any, to be taken to restrict or prevent further use, supply or marketing⁹; (2) withdraw from the market in the United Kingdom and recover possession of such products within the time and for the period specified in the notice¹⁰.

Specific provisions¹¹ regulate the procedure for receiving advice and representations before revocation, variation (otherwise than on the application of the holder) or suspension of a marketing authorisation, and for notifying the holder of that authorisation¹².

1 For the meaning of 'the licensing authority' see PARA 43 note 8 post.

2 For the meaning of 'the relevant Community provisions' see PARA 20 note 1 ante.

3 As to references to marketing authorisations see PARA 20 note 5 ante. For the purposes of the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 6, 'marketing authorisation' includes an authorisation granted by the licensing authority in accordance with EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 126a: Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 6(7A) (added by SI 2005/2759).

4 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 6(1). For the meaning of 'relevant medicinal product' see PARA 20 note 2 ante. For cases relevant to the revocation, suspension or variation of authorisations see: Case C-120/97 *Upjohn Ltd v Licensing Authority established under the Medicines Act 1968* [1999] ECR I-223, 51 BMLR 206, ECJ; Case C-471/00 *Commission of the European Communities v Cambridge Healthcare Supplies Ltd* [2001] ECR I-2865, CFI.

5 For the meaning of 'writing' see PARA 21 note 6 ante.

6 For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

7 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 6(2). In any case where the relevant Community provisions permit or require the suspension of the use, supply or marketing of a product until some decision or similar action is taken by the Community, the licensing authority may, instead of specifying a period in the notice, provide that the suspension is to apply until further notice: reg 6(3). Where the licensing authority includes a provision that the suspension is to apply until further notice, it must, where the effect of the Community decision or action is that the product may continue to be used or, as the

case may be, marketed, in the United Kingdom, promptly give the holder of the authorisation written notice revoking the suspension forthwith or from such date specified in the notice as to comply with that decision or action: reg 6(4). For the meaning of 'the Community' see PARA 20 note 1 ante. It is an offence to sell, supply or market, or procure the sale, supply or marketing of, a product knowing, or having reasonable cause to believe, that such use, supply or marketing is suspended: see PARA 30 post.

8 Ie under ibid reg 6(1)-(4) (see the text and notes 1-7 supra) or the provisions of EC Parliament and Council Regulation 726/2004 (OJ L136, 30.4.2004, p 1).

9 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 6(5)(a) (amended by SI 2005/2759). It is an offence to fail to comply with such notice: see PARA 30 post.

10 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 6(5)(b). The licensing authority may require the holder of the marketing authorisation to withdraw from the market in the United Kingdom specified batches only of a product to which such a notice applies: reg 6(6). See also note 9 supra.

11 As to such provisions see ibid Sch 2; and PARA 26 post.

12 Ibid reg 6(7).

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25. Urgent safety restrictions.

The licensing authority¹ may, subject to and in accordance with the relevant Community provisions², impose an urgent safety restriction on the holder of a United Kingdom marketing authorisation³ or an authorisation granted by the licensing authority in accordance with the Directive⁴ on the Community code relating to medicinal products for human use⁵. Where the licensing authority imposes an urgent safety restriction, the holder of the authorisation must implement the restriction within a period specified by the authority⁶ and apply to vary the authorisation so as to take account of that safety restriction immediately and in any event not later than 15 days after the restriction was imposed⁷.

1 For the meaning of 'the licensing authority' see PARA 43 note 8 post.

2 For the meaning of 'the relevant Community provisions' see PARA 20 note 1 ante.

3 For the meaning of 'United Kingdom marketing authorisation' see PARA 20 note 5 ante.

4 Ie in accordance with EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 126a.

5 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 6A(1) (reg 6A added by SI 2003/2321; and amended by SI 2005/2759). It is an offence to fail to comply with such a restriction: see PARA 30 post.

6 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 6A(2)(a) (as added and amended: see note 5 supra).

7 Ibid reg 6A(2)(b) (as added and amended: see note 5 supra). As to such applications see PARA 26 post.

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26. Procedures relating to grant, renewal, compulsory variation, revocation or suspension of authorisations.

The licensing authority¹ must not, at any time while these provisions apply², refuse to grant or renew the authorisation applied for³, or revoke, vary or suspend⁴ an authorisation⁵, on grounds relating to safety, quality or efficacy, except after consultation with the appropriate committee⁶. Where the appropriate committee is consulted and is of the provisional opinion that, on grounds relating to safety, quality or efficacy, it may be unable to advise the licensing authority to grant or renew the authorisation⁷, or may be unable to advise the licensing authority to grant it unless it contains provisions otherwise than in accordance with the application⁸, or may have to advise the licensing authority that the authorisation ought to be revoked, varied or suspended⁹, the committee must notify the applicant or holder accordingly¹⁰. A person¹¹ who has been so notified may, within the time allowed¹², give notice of his wish to make written or oral representations to the appropriate committee¹³ and the committee must give the applicant or holder an opportunity to make such representations¹⁴. The appropriate committee must take into account such representations as are made¹⁵ and report its findings and advice to the licensing authority, together with the reasons for its advice¹⁶.

After receiving the appropriate committee's report, the licensing authority must take the report into account¹⁷ in deciding whether to refuse to grant or renew the authorisation, or to grant or renew it otherwise than in accordance with the application, or to proceed further with its proposal to revoke, vary or suspend the authorisation¹⁸. The licensing authority must then notify the applicant or holder of its decision¹⁹ and the advice given to it by the appropriate committee and the reasons for that advice²⁰.

A person to whom notification has been given²¹ of a decision made after the receipt of the report of the appropriate committee may, within the time allowed, notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority with respect to the decision²². A person to whom a notification has been given²³ of a decision made in other cases may, within the time allowed, notify the licensing authority that he wishes to appear before and be heard by a person appointed for the purpose by the licensing authority²⁴, or make representations in writing to the licensing authority with respect to the proposal referred to in the notification²⁵.

1 For the meaning of 'the licensing authority' see PARA 43 note 8 post.

2 These provisions apply to:

14 (1) any application for the grant of an authorisation for a relevant medicinal product, except where at any time during the period beginning with the date on which the application is made and ending with the date on which the licensing authority gave a decision on the application, there is a marketing authorisation in force in respect of that product anywhere in the Community, or the application has been submitted to the licensing authority in accordance with EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 28(1) and (3) (Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, regs 5(3), 6(7), Sch 2 para 2(a) (reg 5(3) amended, and Sch 2 substituted, by SI 2005/1094; Sch 2 para 2(a) further substituted by SI 2005/2754);

15 (2) any application to renew an authorisation for a relevant medicinal product (Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 2 para 2(b) (as so substituted)); and

- 16 (3) any proposal to revoke, vary or suspend an authorisation for a relevant medicinal product, other than a variation on the application of the holder of that authorisation (Sch 2 para 2(c) (as so substituted)).

'Authorisation' means a United Kingdom marketing authorisation: Sch 2 para 1 (as so substituted). For the meaning of 'United Kingdom marketing authorisation' see PARA 20 note 5 ante. For the meaning of 'relevant medicinal product' see PARA 20 note 2 ante. For the meaning of 'the Community' see PARA 20 note 1 ante. As to applications see PARAS 22-23 ante. As to variations on the application of the holder of the authorisation see PARA 27 post

The provisions cease to apply if at any time the relevant matter is, by virtue of any relevant Community provision, referred to the Committee for Medicinal Products for Human Use for the application of the procedure laid down in EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) arts 32-34: Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 2 para 5 (as so substituted). For the meaning of 'the relevant Community provisions' see PARA 20 note 1 ante. The Committee for Medicinal Products for Human Use is a committee established under EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) (as amended) to assist the European Commission: see art 21.

The provisions do not apply if:

- 17 (a) the licensing authority rejects, or declines to assess, an application in accordance with EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 17(2) or art 18 (Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 2 para 6(a) (as so substituted)); or
- 18 (b) the application or proposal relates to the renewal, revocation, suspension or variation of a marketing authorisation:
1. (i) which has been granted in accordance with the provisions of EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) Title III, Ch 4, or by member states in accordance with EC Council Directive 87/22 (OJ L15, 17.1.1987, p 38) art 4 before 1 January 1995 (Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 2 para 6(b)(i) (as so substituted)); or
1
 2. (ii) which has not been so granted, but which has been subject to the procedure laid down in EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) arts 32-34 following a referral under art 30 or art 31, unless the procedure was limited to certain specific parts of the authorisation (Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 2 para 6(b)(ii) (as so substituted)).
2
- 3 Ibid Sch 2 para 7(a) (as substituted: see note 2 supra).
- 4 Ibid Sch 2 para 7 (as substituted) does not apply to the suspension of an authorisation (whether or not it applies to any existing proposal to suspend or revoke the authorisation) where it appears to the licensing authority that, in the interests of safety, it is necessary to suspend the authorisation with immediate effect for a period not exceeding three months: Sch 2 para 12(1) (as substituted: see note 2 supra). Where the licensing authority so suspends an authorisation, it must report the suspension forthwith to the appropriate committee: Sch 2 para 12(2) (as so substituted). If, after suspending an authorisation with immediate effect, it appears to the licensing authority, or the appropriate committee advises, that the authorisation ought to be further suspended or ought to be varied or revoked, the licensing authority must proceed in accordance with the applicable provisions of Sch 2 (as substituted) (including Sch 2 para 12 (as substituted)): Sch 2 para 13 (as so substituted). For the meaning of 'month' see PARA 22 note 15 ante.
- 'Appropriate committee', for the purposes of any provision under which a function falls to be performed, means: (1) in a case where a committee has been established under the Medicines Act 1968 s 4 (as amended) (see PARA 15 ante) for purposes which consist of or include any of those specified in s 4(3), and the authority performing that function considers it to be the appropriate committee in the circumstances, that committee; and (2) in any other case, the Commission on Human Medicines: Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 1(2) (definition added by SI 2005/1094). As to the constitution of the Commission see PARA 13 ante.
- 5 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144 Sch 2 para 7(b) (as substituted: see note 2 supra).
- 6 Ibid Sch 2 para 7 (as substituted: see note 2 supra).
- 7 Ibid Sch 2 para 8(1)(a) (as substituted: see note 2 supra).

8 Ibid Sch 2 para 8(1)(b) (as substituted: see note 2 supra).

9 Ibid Sch 2 para 8(1)(c) (as substituted: see note 2 supra).

10 Ibid Sch 2 para 8(1) (as substituted: see note 2 supra).

11 For the meaning of 'person' see PARA 21 note 7 ante.

12 'The time allowed' means the period of 28 days beginning with the date of the relevant notification, or such longer period as the licensing authority may allow in any particular case: Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 2 para 1 (as substituted: see note 2 supra).

13 Ibid Sch 2 para 8(2) (as substituted: see note 2 supra). For the meanings of 'written' and 'writing' see PARA 21 note 6 ante.

14 Ibid Sch 2 para 8(3) (as substituted: see note 2 supra). The applicant or holder must provide the appropriate committee with his written representations or a written summary of the oral representations he intends to make, and any documents on which he wishes to rely in support of those representations, before the end of the period of six months beginning with the date of his notice, or within such shorter period as the appropriate committee may specify in its notification: Sch 2 para 8(4) (as so substituted). If the applicant or holder so requests, the appropriate committee may extend the time limit up to a maximum period of 12 months beginning with the date of the person's notice: Sch 2 para 8(5) (as so substituted). The applicant or holder may not submit any additional written representations or documents once the time limit has expired, except with the permission of the appropriate committee: Sch 2 para 8(6) (as so substituted). If the applicant or holder gave notice of his wish to make oral representations, the appropriate committee must, after receiving a written summary and any other documents, arrange for the applicant or holder to make such representations at a hearing before the committee: Sch 2 para 8(7) (as so substituted).

15 Ibid Sch 2 para 8(8)(a) (as substituted: see note 2 supra).

16 Ibid Sch 2 para 8(8)(b) (as substituted: see note 2 supra).

17 Ibid Sch 2 para 9(1)(b) (as substituted: see note 2 supra).

18 Ibid Sch 2 para 9(1)(a) (as substituted: see note 2 supra).

19 Ibid Sch 2 para 9(2)(a) (as substituted: see note 2 supra).

20 Ibid Sch 2 para 9(2)(b) (as substituted: see note 2 supra).

If the appropriate committee was consulted but did not give a provisional opinion under Sch 2 para 8(1) (as substituted) (see the text to notes 7-10 supra) and the licensing authority proposes:

- 19 (1) to determine an application in a way which differs from the advice of the committee;
- 20 (2) to revoke, vary or suspend a marketing authorisation against such advice; or
- 21 (3) on grounds not relating to safety, quality or efficacy: (a) not to grant or renew an authorisation; (b) to grant or renew an authorisation otherwise than in accordance with an application; or (c) to revoke, vary or suspend an authorisation,

the licensing authority must notify the applicant or holder accordingly: Sch 2 para 10(1) (as so substituted).

If the appropriate committee has not been consulted and the licensing authority proposes, on grounds not relating to safety, quality or efficacy:

- 22 (i) not to grant or renew an authorisation;
- 23 (ii) to grant or renew an authorisation otherwise than in accordance with an application; or
- 24 (iii) to revoke, vary or suspend an authorisation,

the licensing authority must notify the applicant or holder accordingly: Sch 2 para 10(2) (as so substituted).

A notification given under Sch 2 para 10(1), (2) must state the advice of the appropriate committee, if any, and the reasons stated by the committee for any such advice, and the proposals of the licensing authority and the reasons for them: Sch 2 para 10(3) (as so substituted).

21 Ie under ibid Sch 2 para 9(2) (as substituted): see the text to notes 19-20 supra.

22 Ibid Sch 2 para 11(1) (as substituted: see note 2 supra). This provision does not apply where the person has not made any representations in accordance with Sch 2 para 8(4)-(7) (as substituted) (see note 14 supra) and the decision of the licensing authority was in accordance with the advice of the appropriate committee: Sch 2 para 11(4) (as so substituted). As to hearings before the person appointed see PARA 28 post.

23 Ie under ibid Sch 2 para 10(1), (2) (as substituted): see note 20 supra.

24 Ibid Sch 2 para 11(2)(a) (as substituted: see note 2 supra).

25 Ibid Sch 2 para 11(2)(b) (as substituted: see note 2 supra). If the applicant makes written representations, the licensing authority must take those representations into account before determining the matter: Sch 2 para 11(3) (as so substituted).

UPDATE

26 Procedures relating to grant, renewal, compulsory variation, revocation or suspension of authorisations

TEXT AND NOTE 6--SI 1994/3144 Sch 2 para 7 substituted: SI 2009/2820.

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27. Variation of authorisation on application of holder.

If the licensing authority¹ decides, on grounds relating to safety, quality or efficacy, to refuse to grant a Type II variation application², or to grant it otherwise than in accordance with the application³, it must notify the applicant accordingly⁴. A person⁵ who has been so notified may, within the time allowed⁶, give notice to the licensing authority of his wish to make written⁷ or oral representations to the appropriate committee⁸; and, on receipt of the notice, the licensing authority must inform the appropriate committee and the committee must give the applicant an opportunity to make such representations⁹. The appropriate committee must take into account such representations as are made¹⁰ and report its findings and advice to the licensing authority, together with the reasons for that advice¹¹.

After receiving the report of the appropriate committee, the licensing authority must confirm or alter its decision¹² and take the report into account before doing so¹³. The licensing authority must notify the applicant of its decision¹⁴ and the advice given to it by the appropriate committee with the reasons for that advice¹⁵. If the licensing authority notifies the applicant of the authority's decision to refuse the application¹⁶, or to grant it otherwise than in accordance with the application¹⁷, the applicant may, within the time allowed, notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority with respect to the decision¹⁸.

1 For the meaning of 'the licensing authority' see PARA 43 note 8 post.

2 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, regs 5(3), 6(7), Sch 2 para 14(1)(a) (reg 5(3) amended, and Sch 2 substituted, by SI 2005/1094). 'Type II variation application' means an application by the holder of an authorisation to vary that authorisation, if the variation applied for is a major variation of Type II within the meaning of EC Commission Regulation 1084/2003 (OJ L159, 27.6.2003, p 1) art 3(3): Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 2 para 1 (as so substituted). Subject to Sch 2 paras 5, 6 (as substituted) (see PARA 26 note 2 ante), the provisions of Sch 2 Pt 3 paras 14-16 apply to any application to vary an authorisation for a relevant medicinal product which is a Type II variation application: Sch 2 para 3 (as so substituted). For the meaning of 'authorisation' see PARA 26 note 2 ante. For the meaning of 'relevant medicinal product' see PARA 20 note 2 ante.

3 Ibid Sch 2 para 14(1)(b) (as substituted: see note 2 supra).

4 Ibid Sch 2 para 14(1) (as substituted: see note 2 supra).

5 For the meaning of 'person' see PARA 21 note 7 ante.

6 For the meaning of 'the time allowed' see PARA 26 note 12 ante.

7 For the meaning of 'written' see PARA 21 note 4 ante.

8 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 2 para 14(2) (as substituted: see note 2 supra). For the meaning of 'appropriate committee' see PARA 26 note 4 ante.

9 Ibid Sch 2 para 14(3) (as substituted: see note 2 supra). The applicant must provide the appropriate committee with his written representations or a written summary of the oral representations he intends to make, and any documents on which he wishes to rely in support of those representations, before the end of the period of six months beginning with the date of his notice, or within such shorter period as the licensing authority may specify in the notification of its decision: Sch 2 para 14(4) (as so substituted). If the applicant so requests, the appropriate committee may extend the time limit up to a maximum period of 12 months beginning with the date of the applicant's notice: Sch 2 para 14(5) (as so substituted). The applicant may not submit any additional written representations or documents once the time limit has expired, except with the permission of the appropriate committee: Sch 2 para 14(6) (as so substituted). If the applicant gave notice of

his wish to make oral representations, the appropriate committee must, after receiving the written summary and any other documents from the applicant, arrange for the applicant to make such representations at a hearing before the committee: Sch 2 para 14(7) (as so substituted). For the meaning of 'month' see PARA 22 note 15 ante.

10 Ibid Sch 2 para 14(8)(a) (as substituted (see note 2 supra); and further amended by SI 2005/2754).

11 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144 Sch 2 para 14(8)(b) (as substituted: see note 2 supra).

12 Ibid Sch 2 para 15(1)(a) (as substituted: see note 2 supra).

13 Ibid Sch 2 para 15(1)(b) (as substituted: see note 2 supra).

14 Ibid Sch 2 para 15(2)(a) (as substituted: see note 2 supra).

15 Ibid Sch 2 para 15(2)(b) (as substituted: see note 2 supra).

16 Ibid Sch 2 para 16(1)(a) (as substituted: see note 2 supra).

17 Ibid Sch 2 para 16(1)(b) (as substituted: see note 2 supra).

18 Ibid Sch 2 para 16(1) (as substituted: see note 2 supra). This provision does not apply where the person had not made any representations in accordance with Sch 2 para 14(4)-(7) (as substituted) (see note 9 supra) and the decision of the licensing authority was in accordance with the advice of the appropriate committee: Sch 2 para 16(2) (as so substituted).

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28. Hearing before person appointed.

If an applicant or holder of an authorisation¹ gives notice² of his wish to appear before or be heard by a person appointed by the licensing authority³, the authority must make that appointment⁴ and arrange for the applicant or holder to have an opportunity of appearing before that person⁵. The person appointed must not be, or at any time have been, a member of the Commission on Human Medicines or any of its expert advisory groups⁶, the Medicines Commission or any of its committees⁷, or a committee⁸ or any sub-committee of such a committee⁹; nor may he be an officer or servant of a Minister of the Crown¹⁰.

The applicant or holder must, before the end of the period of three months beginning with the date of his notice¹¹, provide the person appointed with a written summary of the oral representations he intends to make¹² and any documents on which he wishes to rely in support of those representations¹³. If the applicant or holder fails to comply with the time limit or any extended time limit, he may not appear before or be heard by the person appointed¹⁴, and the licensing authority must decide whether to confirm or alter its decision¹⁵, to grant or renew the authorisation¹⁶, to grant or renew the authorisation otherwise than in accordance with the application¹⁷, or to revoke, vary or suspend the authorisation¹⁸, as the case may be¹⁹.

At the hearing before the person appointed, both the applicant or holder and the licensing authority may make representations²⁰ and, if the applicant or holder so requests, the hearing must be in public²¹.

After the hearing, the person appointed must provide a report to the licensing authority²²; and the licensing authority must take this report into account and decide whether to confirm or alter its decision²³, to grant or renew the authorisation²⁴, to grant or renew the authorisation otherwise than in accordance with the application²⁵, or to revoke, vary or suspend the authorisation²⁶, as the case may be²⁷. The licensing authority must then notify the applicant or holder of its decision²⁸ and, if the applicant or holder so requests, provide him with a copy of the report of the person appointed²⁹.

1 For the meaning of 'authorisation' see PARA 26 note 2 ante.

2 Ie under the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, regs 5(3), 6(7), Sch 2 paras 11, 16 (reg 5(3) as amended; Sch 2 as substituted): see PARAS 26-27 ante. Subject to Sch 2 paras 5, 6 (as substituted) (see PARA 26 note 2 ante), the provisions of Sch 2 Pt 4 para 17 (as substituted) apply where:

25 (1) an applicant for an authorisation for a relevant medicinal product, or for the variation or renewal of such an authorisation (Sch 2 para 4(a) (Sch 2 substituted by SI 2005/1094)); or

26 (2) the holder of an authorisation for a relevant medicinal product (Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 2 para 4(b) (as so substituted)),

gives notice under Sch 2 paras 11, 16 (as substituted) of his wish to appear before or be heard by a person appointed by the licensing authority (Sch 2 para 4 (as so substituted)). For the meaning of 'relevant medicinal product' see PARA 20 note 2 ante.

3 For the meaning of 'the licensing authority' see PARA 43 note 8 post.

4 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 2 para 17(1) (a) (as substituted: see note 2 supra).

- 5 Ibid Sch 2 para 17(1)(b) (as substituted: see note 2 supra).
- 6 Ibid Sch 2 para 17(2)(a)(i) (as substituted: see note 2 supra). As to the constitution of the Commission on Human Medicines see PARA 13 ante; and as to expert advisory groups see PARA 17 ante.
- 7 Ibid Sch 2 para 17(2)(a)(ii) (as substituted: see note 2 supra). The Medicines Commission was established under the Medicines Act 1968 s 2 (repealed), but has been replaced by the Commission on Human Medicines: see PARA 13 note 1 ante.
- 8 Ie a committee established under ibid s 4 (as amended): see PARA 15 ante.
- 9 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 2 para 17(2)(a)(iii) (as substituted: see note 2 supra).
- 10 Ibid Sch 2 para 17(2)(b) (as substituted: see note 2 supra). As to Ministers of the Crown see CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARA 354 et seq.
- 11 Ibid Sch 2 para 17(3) (as substituted: see note 2 supra). If the applicant or holder so requests, the person appointed may, after consulting the licensing authority, extend the time limit up to a maximum period of six months beginning with the date of the notice: Sch 2 para 17(4) (as so substituted). The applicant or holder may not submit any additional written representations or documents once the time limit has expired, except with the permission of the person appointed: Sch 2 para 17(6) (as so substituted). For the meaning of 'written' see PARA 21 note 4 ante. For the meaning of 'month' see PARA 22 note 15 ante.
- 12 Ibid Sch 2 para 17(3)(a) (as substituted: see note 2 supra).
- 13 Ibid Sch 2 para 17(3)(b) (as substituted: see note 2 supra).
- 14 Ibid Sch 2 para 17(5)(a) (as substituted: see note 2 supra).
- 15 Ibid Sch 2 para 17(5)(b)(i) (as substituted: see note 2 supra).
- 16 Ibid Sch 2 para 17(5)(b)(ii) (as substituted: see note 2 supra).
- 17 Ibid Sch 2 para 17(5)(b)(iii) (as substituted: see note 2 supra).
- 18 Ibid Sch 2 para 17(5)(b)(iv) (as substituted: see note 2 supra).
- 19 Ibid Sch 2 para 17(5)(b) (as substituted: see note 2 supra).
- 20 Ibid Sch 2 para 17(7) (as substituted: see note 2 supra).
- 21 Ibid Sch 2 para 17(8) (as substituted: see note 2 supra).
- 22 Ibid Sch 2 para 17(9)(a) (as substituted: see note 2 supra).
- 23 Ibid Sch 2 para 17(9)(b)(i) (as substituted: see note 2 supra).
- 24 Ibid Sch 2 para 17(9)(b)(ii) (as substituted: see note 2 supra).
- 25 Ibid Sch 2 para 17(9)(b)(iii) (as substituted: see note 2 supra).
- 26 Ibid Sch 2 para 17(9)(b)(iv) (as substituted: see note 2 supra).
- 27 Ibid Sch 2 para 17(9)(b) (as substituted: see note 2 supra).
- 28 Ibid Sch 2 para 17(10)(a) (as substituted: see note 2 supra).
- 29 Ibid Sch 2 para 17(10)(b) (as substituted: see note 2 supra).

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29. Obligations of holders of marketing authorisations.

Every holder of a United Kingdom marketing authorisation¹ for a relevant medicinal product² must comply with all obligations which relate to him by virtue of the relevant Community provisions³ including, in particular, obligations relating to providing or updating information, to making changes, to applying to vary the authorisation, to pharmacovigilance, and to labels and package leaflets⁴. The holder of a marketing authorisation must maintain a record of reports of which he is aware of suspected adverse reactions in accordance with the relevant Community provisions which must be open to inspection by a person authorised by the licensing authority⁵, who may take copies of the record; and, if the licensing authority so directs, the authorisation holder must furnish the licensing authority with a copy of any such reports of which he has a record or of which he is or subsequently becomes aware⁶. The holder of a marketing authorisation must also keep such documents as will facilitate the withdrawal or recall from sale or supply of any relevant medical product to which the authorisation relates⁷. Where, by or under any provision of the relevant Community provisions or of the relevant statutory provisions⁸, a person⁹ is required to provide any information or furnish any document to the licensing authority and no time is specified in that provision within which that obligation is to be performed, it must be performed within such time as may be specified in a written¹⁰ notice served on that person by the licensing authority¹¹.

The holder of a marketing authorisation granted or renewed after 1 January 1995¹² must be established in the Community¹³.

1 For the meaning of 'United Kingdom marketing authorisation' see PARA 20 note 5 ante.

2 For the meaning of 'relevant medicinal product' see PARA 20 note 2 ante.

3 Ie apart from EC Parliament and Council Regulation 726/2004 (OJ L36, 30.4.2004, p 1). For the meaning of 'the relevant Community provisions' see PARA 20 note 1 ante.

4 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 7(1). As to offences by holders of marketing authorisations see PARA 30 post.

5 For the meaning of 'the licensing authority' see PARA 43 note 8 post.

6 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 7(2). For the purposes of reg 7(2)-(4), (6), 'marketing authorisation' includes an authorisation granted by the licensing authority in accordance with EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 126a: Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 7(7) (reg 7(3A), (7) added by SI 2005/2759). Where a person is authorised by the licensing authority to place a product on the market in accordance with EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 126a, he must comply with all obligations under Titles V, VI, VIII, IX and XI of that Directive which would apply to him by virtue of those provisions and the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144 (as amended) if he were the holder of a United Kingdom marketing authorisation for that product: reg 7(3A) (as so added).

7 Ibid reg 7(3). See also note 6 supra.

8 Ie the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144 (as amended).

9 For the meaning of 'person' see PARA 21 note 7 ante.

10 For the meaning of 'written' see PARA 21 note 4 ante.

11 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 7(5). It is an offence to fail to comply with such a notice: see PARA 30 post.

12 Ie the date of the coming into force of the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144: see regs 1(1), 7(6).

13 Ibid reg 7(6). See also note 6 supra. For the meaning of 'the Community' see PARA 20 note 1 ante.

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30. Offences.

A person¹ is guilty of an offence² if:

- 36 (1) in breach of the relevant Community provisions³ or the relevant statutory provisions⁴, he places a relevant medicinal product⁵ on the market without holding a Community or United Kingdom marketing authorisation⁶ in respect of that product, or otherwise than in accordance with the terms of such an authorisation⁷;
- 37 (2) in respect of any product which is a relevant medicinal product⁸, the licensing authority⁹ serves a notice¹⁰ in respect of that product on him requiring him:
 - 3 (a) to stop marketing the product from a date specified in the notice unless or until a marketing authorisation, traditional herbal registration¹¹ or certificate of registration¹² is granted in respect of that product, and after the date specified he places that product on the market¹³, or in the course of a business carried on by him, he sells, supplies to a member of the public or procures for sale or for supply to a member of the public that product¹⁴, without a marketing authorisation, traditional herbal registration or certificate of registration having been granted in respect of that product¹⁵;
 - 4 (b) not to place the product on the market unless or until a marketing authorisation, traditional herbal registration or certificate of registration is granted in respect of that product, and he thereafter places the product on the market without a marketing authorisation, traditional herbal registration or certificate of registration having been granted in respect of that product¹⁶;
- 4 38 (3) he places a generic medicinal product on the market before the following periods have elapsed from the date of the initial authorisation, namely:
 - 5 (a) in a case where during the first eight years after the grant of the initial marketing authorisation of the reference medicinal product the holder of that authorisation is granted an authorisation for a new therapeutic indication of significant clinical benefit¹⁷, 11 years¹⁸; and
 - 6 (b) in any other case, ten years¹⁹;
- 6 39 (4) in the course of a business carried on by him, he sells, supplies, manufactures or assembles²⁰, or procures the sale, supply, manufacture or assembly of, a relevant medicinal product, or has in his possession a relevant medicinal product, knowing or having reasonable cause to believe that the product was or is intended to be placed on the market contrary to head (1) or head (3) above²¹;
- 40 (5) without prejudice to any other sanction which may be available for the enforcement of conditions attaching to marketing authorisations, he is the holder of a marketing authorisation for a relevant medicinal product and contravenes any condition of the authorisation²²;
- 41 (6) being the holder of a marketing authorisation, he fails to implement an urgent safety restriction imposed²³ on him by the licensing authority²⁴;
- 42 (7) where the use, supply or marketing of a relevant medicinal product is suspended²⁵, he sells, supplies or markets, or procures the sale, supply or

marketing of, that product knowing, or having reasonable cause to believe, that such use, supply or marketing is suspended²⁶;

43 (8) he is or, immediately before its revocation or suspension, was the holder of a marketing authorisation and fails to comply with a notice given to him²⁷ requiring that he take all reasonably practicable steps to publish information concerning revocation or suspension or to recover possession of products affected²⁸;

44 (9) being the holder of a marketing authorisation, he fails promptly to take certain steps or to provide certain information²⁹;

45 (10) being the holder of a United Kingdom marketing authorisation, he fails to forward to the licensing authority any data requested³⁰ by the authority:

7

7. (a) where the licensing authority has served a written notice³¹ on the holder in relation to the request, within the time specified in that notice³²; or

8. (b) where there is no such notice, promptly³³;

8

46 (11) being a person responsible for placing on the market a relevant medicinal product authorised by the Community or by the licensing authority he, at any time, does not have at his disposal an appropriately qualified person³⁴ responsible for pharmacovigilance³⁵;

47 (12) being a person responsible for placing a relevant medicinal product on the market, he fails³⁶ to report to the licensing authority any suspected adverse reaction, or to submit to the licensing authority any records of suspected adverse reactions³⁷;

48 (13) being a person responsible for placing a relevant medicinal product on the market, he fails to make or maintain³⁸ a detailed record of any suspected adverse reaction³⁹;

49 (14) while employed or engaged as an appropriately qualified person responsible for pharmacovigilance⁴⁰, he fails to comply with certain requirements⁴¹;

50 (15) being a holder of a marketing authorisation, he sells or supplies or procures the sale or supply of a relevant medicinal product to which the authorisation relates, the labelling of which, or any package leaflet accompanying which, does not comply with the applicable requirements⁴², or without a package leaflet required to be provided⁴³ by virtue of those requirements⁴⁴;

51 (16) in relation to a relevant medicinal product, the labelling of the product or any package leaflet accompanying the product does not comply with⁴⁵, or the product is not accompanied by a package leaflet required to be provided by virtue of⁴⁶, the applicable requirements⁴⁷, and he is a person, other than the holder of the marketing authorisation for that product, who in the course of a business carried on by him, sells or supplies or procures the sale or supply of that product knowing, or having reasonable cause to believe, that the labelling does not so comply or, as the case may be, that the product is not so accompanied⁴⁸;

52 (17) he fails to keep any record required⁴⁹, or to give notice or make a record available for inspection as and when required⁵⁰;

53 (18) he distributes⁵¹ a relevant medicinal product by way of wholesale dealing⁵² without there being a marketing authorisation in respect of that product⁵³;

54 (19) being the holder of a Community marketing authorisation, he fails to provide the EMEA with any data requested⁵⁴ within the time specified in the request, if a time within which to provide the data to the EMEA is so specified⁵⁵, or promptly, if no such time is specified⁵⁶;

55 (20) being the holder of a Community or United Kingdom marketing authorisation, he communicates to the general public information relating to pharmacovigilance concerns about the product to which the authorisation relates⁵⁷ without having previously communicated, or without simultaneously communicating, such information to the EMEA, in the case of a product for which

there is a Community marketing authorisation, or otherwise to the licensing authority⁵⁸;

- 56 (21) being a person who is the holder of a Community or United Kingdom marketing authorisation⁵⁹, he fails to ensure that the information which he communicates to the general public, the licensing authority or the EMEA relating to pharmacovigilance concerns about the product to which his authorisation relates is presented objectively and is not misleading⁶⁰.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 As to the penalties, and as to a defence to such offences, see PARA 32 post. As to offences where there is a defence of reasonable precaution and due diligence see PARA 31 post.

3 For the meaning of 'the relevant Community provisions' see PARA 20 note 1 ante.

4 Ie the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144 (as amended).

5 For the meaning of 'relevant medicinal product' see PARA 20 note 2 ante.

6 For the meanings of 'Community marketing authorisation' and 'United Kingdom marketing authorisation' see PARA 20 note 5 ante. For the purposes of the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 7(4), Sch 3 paras 1, 3, 3A, 4, 5, 6E, 6F, 11, and 12 (Sch 3 paras 3A, 6E, 6F as added; Sch 3 paras 11, 12 as amended), 'marketing authorisation' includes an authorisation granted by the licensing authority in accordance with EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 126a: Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 18 (added by SI 2005/2759).

7 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 1.

8 For the purposes of ibid Sch 3 para 1A, 'relevant medicinal product' means a medicinal product for human use to which the provisions of EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) (as amended) apply: Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 1A(2) (Sch 3 para 1A as added (see note 13 infra); Sch 3 para 1A(2) added by SI 2005/2759).

9 For the meaning of 'the licensing authority' see PARA 43 note 8 post.

10 Ie under the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 3A(6) (as added) following a determination under reg 3A(4), (5) (as added): see PARA 21 ante.

11 For the meaning of 'traditional herbal registration' see PARA 20 note 2 ante.

12 For the meaning of 'certificate of registration' see PARA 21 note 4 ante.

13 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 1A(1)(a)(i) (Sch 3 para 1A added by SI 2000/292; and the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 1A(1) renumbered and amended by SI 2005/2759).

14 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 1A(1)(a)(ii) (as added, renumbered and amended: see note 13 supra).

15 Ibid Sch 3 para 1A(1)(a) (as added, renumbered and amended: see note 13 supra).

16 Ibid Sch 3 para 1A(1)(b) (as added, renumbered and amended: see note 13 supra).

17 Ie as set out in EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 10(1).

18 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 1AA(a) (Sch 3 para 1AA added by SI 2005/2759).

19 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 1AA(b) (as added: see note 18 supra).

20 As to the meaning of 'manufacture' see PARA 7 note 2 ante. For the meaning of 'assemble' see PARA 6 note 8 ante.

- 21 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 2 (amended by SI 2005/2759).
- 22 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 3. See also note 6 supra.
- 23 Ie under ibid reg 6A (as added) (see PARA 25 ante) or by the European Commission under EC Commission Regulation 1085/2003 (OJ L159, 27.6.2003, p 24).
- 24 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 3A (added by SI 2003/2321). See also note 6 supra.
- 25 Ie in accordance with the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 6 (see PARA 24 ante) or EC Parliament and Council Regulation 726/2004 (OJ L136, 30.4.2004, p 1).
- 26 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 4 (amended by SI 2005/2759). See also note 6 supra.
- 27 Ie under the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 6(5): see PARA 24 ante.
- 28 Ibid Sch 3 para 5. See also note 6 supra.
- 29 Ibid Sch 3 para 6. The matters to which this provision applies are:
 - 27 (1) updating information concerning the product or any connected matter as required by EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 8.3 or EC Council Regulation 2309/93 (OJ L214, 24.8.1993, p 1) art 6 (Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 6(a) (amended by SI 2002/236)); or
 - 28 (2) taking any steps reasonably necessary to take account of technical and scientific progress for the purposes of making any changes or amendments as required by EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 23 or EC Parliament and Council Regulation 726/2004 (OJ L136, 30.4.2004, p 1) art 16.1 (Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 6(b) (amended by SI 2002/236; SI 2005/2759)); or
 - 29 (3) introducing any changes or making any amendments that may be required in accordance with those articles or EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) Annex I Pt I paras 3.2(9), 3.2.1.2(c) and 3.2.2.4(c) (Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 6(c) (amended by SI 2000/292; SI 2003/2321)); or
 - 30 (4) providing information to the licensing authority as required by EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 23 (third or fourth paragraphs) or art 23a (first paragraph) (Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 6(cc) (added by SI 2004/3224; and amended by SI 2005/2759)); or
 - 31 (5) providing information to the EMEA, the Commission or the licensing authority as required by EC Parliament and Council Regulation 726/2004 (OJ L136, 30.4.2004, p 1) art 16.2 (Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 6(d) (amended by SI 2005/2759));
 - 32 (6) providing information to the EMEA as required by EC Parliament and Council Regulation 726/2004 (OJ L136, 30.4.2004, p 1) art 13(4) (first or second paragraphs) (Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 6(dd) (added by SI 2005/2759)); or
 - 33 (7) submitting any application to the licensing authority or the Community to make any changes or variation as required by EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 23 or EC Parliament and Council Regulation 726/2004 (OJ L136, 30.4.2004, p 1) art 16.3 (Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 6(e) (amended by SI 2002/236; SI 2005/2759)).

'The EMEA' means the European Medicines Agency established by EC Parliament and Council Regulation 726/2004 (OJ L136, 30.4.2004, p 1): Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994,

SI 1994/3144, reg 1(2) (definition substituted by SI 2004/3224). For the meaning of 'the Community' see PARA 20 note 1 ante.

30 Ie pursuant to EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 23 (final paragraph) or art 23a (final paragraph).

31 Ie under the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 7(5): see PARA 29 ante.

32 Ibid Sch 3 para 6A(a) (Sch 3 para 6A added by SI 2004/3224; and the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 6A(a) amended by SI 2005/2759).

33 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 6A(b) (as added: see note 32 supra).

34 Ie as required by EC Parliament and Council Regulation 726/2004 (OJ L136, 30.4.2004, p 1) or EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) Title IX.

35 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 7 (Sch 3 paras 7-10 amended by SI 2002/236; SI 2005/2759). For the purposes of the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 paras 7-10 the requirements referred to in those paragraphs are deemed to apply in relation to the holder of an authorisation granted by the licensing authority in accordance with EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 126a as they apply to the holder of a marketing authorisation: Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 19 (added by SI 2005/2759).

36 Ie contrary to the requirements of EC Parliament and Council Regulation 726/2004 (OJ L136, 30.4.2004, p 1) or EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) Title IX.

37 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 8 (as amended: see note 35 supra). See also note 35 supra. Where such an offence is committed by a person who is acting as the employee or agent of another person, the employer or principal of that person is guilty of the same offence: Sch 3 para 15(1).

38 Ie as required by EC Parliament and Council Regulation 726/2004 (OJ L136, 30.4.2004, p 1) or EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) Title IX.

39 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 9 (as amended: see note 35 supra). See also note 35 supra. Where such an offence is committed by a person who is acting as the employee or agent of another person, the employer or principal of that person is guilty of the same offence: Sch 3 para 15(1).

40 Ie for the purposes of EC Parliament and Council Regulation 726/2004 (OJ L136, 30.4.2004, p 1) or EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) Title IX.

41 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 10 (as amended: see note 35 supra). The requirements are to:

- 34 (1) establish or maintain a system for collecting and collating information about suspected adverse reactions (Sch 3 para 10(a) (as so amended));
- 35 (2) prepare for the licensing authority a report on any such reactions (Sch 3 para 10(b) (as so amended));
- 36 (3) ensure that a request from the licensing authority for the provision of additional information necessary for the evaluation of the benefits and risks afforded by a relevant medicinal product is answered fully and promptly (Sch 3 para 10(c) (as so amended)); or
- 37 (4) provide to the licensing authority any other information relevant to the evaluation of the benefits and risks afforded by a medicinal product, including appropriate information on post authorisation safety studies (Sch 3 para 10(d) (as so amended)),

as required by any provision of EC Parliament and Council Regulation 726/2004 (OJ L136, 30.4.2004, p 1) or EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) Title IX: Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 10 (as so amended). See also note 35 supra. Where an offence is committed under Sch 3 para 10 (as amended) by a person who is acting as the employee or agent of another person, the employer or principal of that person is guilty of the same offence: Sch 3 para 15(1).

42 Ibid Sch 3 para 11(a). As to the applicable requirements see EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) Title V; the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 5 (amended by SI 1998/3105; SI 2000/292; SI 2002/236; SI 2002/542; SI 2003/1618); the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 5A (added by SI 1998/3105).

43 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 11(b).

44 Ibid Sch 3 para 11 (Sch 3 paras 11, 12 amended by SI 1998/3105; SI 2002/236). See also note 6 supra.

45 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 12(a).

46 Ibid Sch 3 para 12(b).

47 Ie those of ibid Sch 5 (as amended) and Sch 5A (as added) or EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) Title V (see note 42 supra).

48 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 12 (as amended: see note 44 supra). See also note 6 supra.

49 Ie under ibid Sch 1 para 6: see PARA 20 ante.

50 Ibid Sch 3 para 13. As to the requirement relating to inspection of records see Sch 1 para 7; and PARA 20 ante.

51 Ie contrary to ibid reg 3(1)(b): see PARA 20 ante.

52 For the meaning of 'wholesale dealing' see PARA 47 note 5 post.

53 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 2A (Sch 3 paras 2A, 6D-6F added by SI 2005/2759).

54 Ie pursuant to EC Parliament and Council Regulation 726/2004 (OJ L136, 30.4.2004, p 1) art 13(4) (final paragraph) or art 26 (final paragraph).

55 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 6D(a) (as added: see note 53 supra).

56 Ibid Sch 3 para 6D(b) (as added: see note 53 supra).

57 Ibid Sch 3 para 6E(a) (as added: see note 53 supra).

58 Ibid Sch 3 para 6E(b) (as added: see note 53 supra). See also note 6 supra.

59 Ibid Sch 3 para 6F(a) (as added: see note 53 supra).

60 Ibid Sch 3 para 6F(b) (as added: see note 53 supra). See also note 6 supra.

UPDATE

30 Offences

NOTES 3-7--See *R v Patel* [2009] EWCA Crim 2311, [2010] 1 WLR 1011, [2009] All ER (D) 150 (Nov) (transactions which neither intended, nor had, effect of releasing medicinal product into a distribution system that led to its sale to end users within the Community not prohibited).

NOTE 29--Head (1) for 'EC Council Regulation 2309/93 (OJ L214, 24.8.1993, p 1) art 6' read 'EC Council Regulations 726/2004 art 6': SI 1994/3144 Sch 3 para 6(a) (amended by SI 2006/1952). SI 1994/3144 Sch 3 para 6(cc) further amended: SI 2006/1952, SI 2008/3097. SI 1994/3144 Sch 3 para 6(e) further amended, Sch 3 para 6(f) added: SI 2008/3097. For further clarification as to the information that must be provided as

specified by SI 1994/3144 Sch 3 para 6(cc), see Sch 3 para 6AA (added by SI 2008/3097).

NOTE 41--SI 1994/3144 Sch 3 para 10(d) substituted: SI 2008/3097.

NOTE 42--SI 1994/3144 Sch 5 further amended: SI 2009/1164.

NOTE 44--SI 1994/3144 Sch 3 paras 11, 12 further amended: SI 2008/3097.

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31. Offences where there is a defence of reasonable precaution and due diligence.

Any person¹ is guilty of an offence² if he is a person who:

- 57 (1) in the course of an application for the grant, renewal or variation of a marketing authorisation³ for a relevant medicinal product⁴:
- 9
9. (a) fails to provide to the licensing authority⁵ any information⁶ which is relevant to an evaluation of the safety, quality or efficacy of the relevant medicinal product⁷; or
10. (b) provides to the licensing authority any information which is relevant to an evaluation of the safety, quality or efficacy of the relevant medicinal product but which is false or misleading in a material particular⁸;
- 10
- 58 (2) is: (a) responsible for placing a relevant medicinal product on the market⁹; (b) the marketing authorisation holder for a relevant medicinal product¹⁰; or (c) required, while employed or engaged as an appropriately qualified person responsible for pharmacovigilance¹¹, to provide information to the licensing authority about a relevant medicinal product¹², and provides to the licensing authority any information which is relevant to an evaluation of the safety, quality or efficacy of the relevant medicinal product but which is false or misleading in a material particular¹³;
- 59 (3) sells or supplies¹⁴ a relevant medicinal product¹⁵, or provides a specification¹⁶ for such a product¹⁷, and provides to the licensing authority any information which is relevant to an evaluation of the safety, quality or efficacy of the relevant medicinal product but which is false or misleading in a material particular¹⁸;
- 60 (4) is the holder of a United Kingdom marketing authorisation¹⁹ who fails, not less than two months²⁰ before an interruption in the placing on the market of the product to which the authorisation relates, to notify the licensing authority that the product is to cease to be placed on the market²¹;
- 61 (5) is the holder of a Community²² or United Kingdom marketing authorisation who fails to ensure²³ appropriate and continued supplies²⁴.

A person does not commit any of the above offences if he took all reasonable precautions and exercised all due diligence to avoid the commission of that offence²⁵. Where evidence is adduced which is sufficient to raise an issue with respect to that defence, the court or jury must assume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not²⁶.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 7(4), Sch 3 paras 10A(1), (2), 13A (Sch 3 paras 10A, 13A added by SI 2005/1710). As to the penalties for such offences see PARA 32 post.

3 As to references to marketing authorisations see PARA 20 note 5 ante. As to applications for the grant, renewal or variation of marketing authorisations see PARA 22 ante.

4 For the meaning of 'relevant medicinal product' see PARA 20 note 2 ante.

- 5 For the meaning of 'the licensing authority' see PARA 43 note 8 post.
- 6 le as required by EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) Annex I introduction point (7) or (11).
- 7 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 10A(1)(a) (as added: see note 2 supra). Where an offence is committed under Sch 3 para 10A (as added) by a person who is acting as the employee or agent of another person, the employer or principal of that person is guilty of the same offence: Sch 3 para 15(1) (amended by SI 2005/1710).
- 8 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 10A(1)(b) (as added: see note 2 supra). See also note 7 supra.
- 9 Ibid Sch 3 para 10A(2)(a) (as added: see note 2 supra).
- 10 Ibid Sch 3 para 10A(2)(b) (as added: see note 2 supra).
- 11 le for the purposes of EC Council Regulation 2309/93 (OJ L214, 24.8.1993, p 1) Title II Ch 3 or EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) Title IX.
- 12 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 10A(2)(c) (as added: see note 2 supra).
- 13 Ibid Sch 3 para 10A(2) (as added: see note 2 supra). See also note 7 supra.
- 14 le in accordance with ibid Sch 1 paras 1-4: see PARA 20 ante.
- 15 Ibid Sch 3 para 13A(a) (as added: see note 2 supra).
- 16 le for the purposes of ibid Sch 1 para 1: see PARA 20 ante.
- 17 Ibid Sch 3 para 13A(b) (as added: see note 2 supra).
- 18 Ibid Sch 3 para 13A (as added: see note 2 supra).
- 19 For the meaning of 'United Kingdom marketing authorisation' see PARA 20 note 5 ante.
- 20 For the meaning of 'month' see PARA 22 note 15 ante.
- 21 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 6B (Sch 3 paras 6B, 6C added by SI 2005/2759).
- 22 For the meaning of 'Community marketing authorisation' see PARA 20 note 5 ante.
- 23 le pursuant to EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 81 (second paragraph).
- 24 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 6C (as added: see note 21 supra).
- 25 Ibid Sch 3 para 17(1) (Sch 3 para 17 added by SI 2005/1710; and the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 17(1) amended by SI 2005/2759). As to a further defence see PARA 32 post.
- 26 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 17(2) (as added: see note 25 supra). As to the standard of proof in criminal trials generally see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(3) (2006 Reissue) PARA 1368 et seq.

UPDATE

31 Offences where there is a defence of reasonable precaution and due diligence

TEXT AND NOTES--See also SI 1994/3144 Sch 3 paras 6BA, 6BB, 6G and 13B (added by SI 2008/3097) which set out various criminal offences enforcing the provisions of

European Parliament and EC Council Regulation 1901/2006 on medicinal products for paediatric use.

NOTE 25--SI 1994/3144 Sch 3 para 17(1) further amended to apply the defence of reasonable precaution and due diligence to offences under Sch 3 paras 6BA, 6BB, 6G and 13B: SI 2008/3097.

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32. Penalties and general defence.

Any person¹ guilty of an offence² is liable to a fine or to imprisonment or, in some cases, to both³.

Where the holder of a marketing authorisation⁴ is charged with an offence in respect of anything which has been manufactured⁵ or assembled⁶ to his order by another person and had been so manufactured or assembled as not to comply with the provisions of that authorisation, it is a defence for him to prove that he had communicated the provisions relating to the authorisation to that other person⁷ and that he did not know, and could not by the exercise of reasonable care have known, that those provisions had not been complied with⁸.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 As to offences under the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144 (as amended) see PARAS 30-31 ante.

3 See *ibid* reg 7(4), Sch 3 para 14. The penalty on summary conviction is a fine not exceeding the statutory maximum, and on conviction on indictment is a fine or imprisonment for a term not exceeding two years or both: Sch 3 para 14(a), (b). The 'statutory maximum', with reference to a fine or penalty on summary conviction for an offence, is the prescribed sum within the meaning of the Magistrates' Courts Act 1980 s 32 (as amended): see the Interpretation Act 1978 s 5, Sch 1 (definition added by the Criminal Justice Act 1988 s 170(1), Sch 15 para 58); and SENTENCING AND DISPOSITION OF OFFENDERS vol 92 (2010) PARA 140; MAGISTRATES vol 29(2) (Reissue) PARA 804. The 'prescribed sum' means £5,000 or such sum as is for the time being substituted in this definition by order under the Magistrates' Courts Act 1980 s 143(1) (as substituted): see s 32(9) (amended by the Criminal Justice Act 1991 s 17(2)); and SENTENCING AND DISPOSITION OF OFFENDERS vol 92 (2010) PARA 141.

4 As to references to marketing authorisations see PARA 20 note 5 ante. For the purposes of the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 16, 'marketing authorisation' includes an authorisation granted by the licensing authority in accordance with EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 126a: Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 18 (added by SI 2005/2759). For the meaning of 'the licensing authority' see PARA 43 note 8 post.

5 As to the meaning of 'manufacture' see PARA 7 note 2 ante.

6 For the meaning of 'assemble' see PARA 6 note 8 ante.

7 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 3 para 16(a).

8 *Ibid* Sch 3 para 16(b).

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33. Enforcement.

The enforcement provisions of the Medicines Act 1968¹, apply, with certain modifications², for the purposes of the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994³ as they apply for the purposes of the Act⁴, and as if all relevant medicinal products⁵ were medicinal products⁶ for the purposes of the Act, whether or not they would otherwise be so⁷.

1 le the following provisions of the Medicines Act 1968: ss 107-108 (see PARAS 79, 168 post), ss 111-116 (see PARAS 169-173 post), ss 118, 119 (see PARAS 174-175 post), ss 121-126 (see PARAS 179-181, 183-184 post), s 127 (see PARA 37 note 8 post) and Sch 3 (see PARA 171 post).

2 le the modifications specified in the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 10(2)(a), Sch 4.

3 le the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144 (as amended): see PARAS 20-32 ante.

4 Ibid reg 10(1).

5 For the meaning of 'relevant medicinal product' see PARA 20 note 2 ante.

6 For the meaning of 'medicinal product' see PARA 7 ante.

7 Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 10(2)(b).

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(iv) Veterinary Medicinal Products

A. MARKETING AUTHORISATIONS

34. Placing veterinary medicinal products on the market.

No person¹ may place on the market, or import² for the purposes of placing on the market or have in his possession for those purposes, any veterinary medicinal product³ unless a marketing authorisation or allowance⁴ has been granted by the ministers⁵ or in accordance with specified provisions⁶, and it is placed on the market in accordance with such authorisation or allowance⁷. However, these restrictions do not apply to the importation of a ready-made veterinary medicinal product⁸ from another member state⁹ or to its subsequent sale or supply¹⁰, provided that the product is carried into the United Kingdom¹¹ by a veterinary surgeon who practises both in that other EEA state¹² and in the United Kingdom, and who complies with certain requirements¹³.

Various provisions of the Medicines Act 1968 apply to marketing authorisations as they apply to product licences granted under the Act¹⁴. The provisions of the Trade Descriptions Act 1968 apply to the application of a trade description to goods subject to a marketing authorisation in the same way as they apply¹⁵ to the application of a trade description to goods subject to the provisions of the Medicines Act 1968 relating to containers, packages and product identification¹⁶; and the provisions of the Consumer Protection Act 1987 apply to a product for which a marketing authorisation has been granted¹⁷.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 For the meaning of 'import' see PARA 7 note 3 ante; definition applied by the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 18(2).

3 The Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142 (as amended) apply in respect of products to which EC Parliament and Council Directive 2001/82 (OJ L311, 28.11.2001, p 1) applies by virtue of arts 2, 3; they do not apply to products specified in art 4.1 but do apply to products intended for the uses set out in art 4.2: Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 1(2) (reg 1(2), (3) substituted by SI 2002/269). The regulations apply to homoeopathic veterinary medicinal products other than those specified in EC Parliament and Council Directive 2001/82 (OJ L311, 28.11.2001, p 1) art 17.1: Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 1(3) (as so substituted). The regulations do not apply to:

- 38 (1) the placing on the market of veterinary medicinal products prepared extemporaneously in the circumstances described in EC Parliament and Council Directive 2001/82 (OJ L311, 28.11.2001, p 1) (Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 2(1) (reg 2 substituted by SI 2002/269));
- 39 (2) the placing on the market of veterinary medicinal products under the Medicines Act 1968 ss 32-39 (see PARA 127 et seq post) (Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 2(2) (as so substituted));
- 40 (3) any product which by virtue of reg 19(1) (transitional provisions) continues to have a product licence under the Medicines Act 1968 s 7 (see PARA 44 post) so long as that licence remains in force (Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 2(3) (as so substituted)).

4 le in the circumstances described in EC Parliament and Council Directive 2001/82 (OJ L311, 28.11.2001, p 1) art 8, an allowance within the terms of that article: Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 3 (reg 3 substituted by SI 2002/269).

5 Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 3(a) (as substituted: see note 4 supra). Any function conferred on the ministers may be performed by any one of those ministers acting alone or by any two or more of them acting jointly: reg 1(5). For the meaning of 'the ministers' see PARA 3 note 3 ante.

6 Ibid reg 3(b) (as substituted: see note 4 supra). The specified provisions are those of EC Council Regulation 2309/93 (OJ L214, 24.8.1993, p 1) (as amended): see PARA 19 ante.

7 Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 3 (as substituted: see note 4 supra). It is an offence to contravene this provision: see PARA 39 post. As to admissible evidence in cases alleging contravention see *Department for the Environment, Food and Rural Affairs v Atkinson* [2002] EWHC 2029 (Admin), [2002] All ER (D) 116 (Oct), DC.

8 'Ready-made veterinary medicinal product' has the meaning given by EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) on the approximation of the laws of the member states relating to veterinary medicinal products art 1.2 (amended by EC Council Directive 90/676 (OJ L373, 31.12.1990, p 26)): Medicines (Veterinary Medicinal Products) (Veterinary Surgeons from Other EEA States) Regulations 1994, SI 1994/2986, reg 2.

9 For the meaning of 'member state' see the European Communities Act 1972 s 1(2), Sch 1 Pt II; and the Interpretation Act 1978 s 5, Sch 1.

10 Medicines (Veterinary Medicinal Products) (Veterinary Surgeons from Other EEA States) Regulations 1994, SI 1994/2986, reg 3(1) (substituted by SI 1994/3142)002E

11 For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

12 'EEA state' means a state which is a contracting party to the EEA Agreement other than the United Kingdom: Medicines (Veterinary Medicinal Products) (Veterinary Surgeons from Other EEA States) Regulations 1994, SI 1994/2986, reg 2. 'EEA Agreement' is not defined for these purposes; cf the definitions in the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031 (as amended) (see PARA 82 note 1 post) and the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322 (see PARA 212 note 2 post).

13 Medicines (Veterinary Medicinal Products) (Veterinary Surgeons from Other EEA States) Regulations 1994, SI 1994/2986, reg 3(2). The requirements are those of EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 4.5 (amended by EC Council Directive 90/676 (OJ L373, 31.12.1990, p 26)): Medicines (Veterinary Medicinal Products) (Veterinary Surgeons from Other EEA States) Regulations 1994, SI 1994/2986, reg 3(2). As to veterinary surgeons see ANIMALS vol 2 (2008) PARA 1126 et seq.

14 Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 18(2). The provisions of the Medicines Act 1968 referred to in the text are: s 23 (special provisions as to effect of manufacturer's licence) (see PARA 66 post), s 40 (medicated animal feeding stuffs) (see AGRICULTURAL PRODUCTION AND MARKETING vol 1 (2008) PARA 996 et seq), ss 51-54 (provisions as to sale or supply of medicinal products) (see PARAS 133-136 post), ss 55-57 (exemptions from ss 52, 53) (see PARAS 137-139 post), ss 58-63 (additional provisions) (see PARAS 140-144, 146 post), ss 85, 86 (labelling and marking) (see PARAS 152-153 post), ss 92-97 (promotion of sales of medicinal products) (see PARAS 157-166 post), s 127 (service of documents) (see PARA 37 note 8 post), s 132 (interpretation), s 133(2) (general provisions as to operation of the Act) (see PARA 10 ante): Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 18(2).

In the Medicines Act 1968 ss 3, 4 (see PARAS 14-15 ante), which relate to the Commission for Human Medicines and committees, any function of the Commission or a committee relating to product licences applies to marketing authorisations in the same way as it applies to licences: Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 18(3). As to the constitution of the Commission see PARA 13 ante.

In the Medicines Act 1968 ss 32-39 (see PARA 126 et seq post), which relate to animal tests, a marketing authorisation granted under the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142 (as amended) is sufficient for any requirement in those provisions that any person must be in possession of a product licence: reg 18(4). The Medicines Act 1968 s 7 (which requires, inter alia, the products to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142 (as amended) apply to be the subject of product licences: see PARA 44 post) does not apply to the placing on the market, or import for those purposes, of a veterinary medicinal product to which the regulations apply except for those products which are to retain product licences by virtue of the provisions of reg 19(1) (which applies to product licences existing on 1 January 1995 granted for certain veterinary medicinal products): reg 18(1) (amended by SI 2000/776).

15 le by virtue of the Trade Descriptions Act 1968 s 2(5)(b) (as added): see SALE OF GOODS AND SUPPLY OF SERVICES vol 41 (2005 Reissue) PARA 482.

16 Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 18(5). The relevant provisions of the Medicines Act 1968 are those of Pt V (ss 85-91) (as amended): see PARAS 152-156 post.

17 Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 18(6). The provisions apply in the same way as they apply to a licensed medicinal product as defined in the Consumer Protection Act 1987 s 19 (see SALE OF GOODS AND SUPPLY OF SERVICES vol 41 (2005 Reissue) PARA 534): Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 18(6).

UPDATE

34-41 Veterinary Medical Products

SI 1994/2986, SI 1994/2987, SI 1994/3142, SI 1997/322, SI 1998/1046, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. As to marketing and other authorisations see now the Veterinary Medicines Regulations 2009, SI 2009/2297; and PARAS 34A-34D.

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34A. Veterinary medical products: general provisions.

1. Regulation

Provision has been made for the authorisation, manufacture, classification, distribution and administration of veterinary medical products¹. 'Veterinary medicinal product' means any substance or combination of substances presented as having properties for treating or preventing disease in animals², or any substance or combination of substances that may be used in, or administered to, animals with a view either to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis³.

The Secretary of State must specify the classification of the veterinary medicinal product when granting the initial marketing authorisation⁴. The categories of authorised veterinary medicinal products are (1) Prescription Only Medicine--Veterinarian; (2) Prescription Only Medicine--Veterinarian, Pharmacist, Suitably Qualified Person; (3) Non-Food Animal--Veterinarian, Pharmacist, Suitably Qualified Person; (4) Authorised Veterinary Medicine--General Sales List⁵.

The provisions do not apply to a veterinary medicinal product based on radio-active isotopes⁶. Nor do they apply in relation to a product intended for administration in the course of a licensed procedure⁷, except that, if the animals are to be put into the human food chain, the only products that may be administered to the animals are (a) authorised veterinary medicinal products administered in accordance with their marketing authorisation, or (b) products administered in accordance with an animal test certificate⁸. Further, the provisions do not apply to an inactivated autogenous vaccine that is manufactured, on the instructions of a veterinary surgeon, from pathogens or antigens obtained from an animal and used for the treatment of that animal⁹.

A veterinary medicinal product is authorised to be placed on the market without a marketing authorisation if it complies with specified provisions¹⁰, where that product is intended solely for certain small animals¹¹ kept exclusively as a pet¹².

1 See the Veterinary Medicines Regulations 2009, SI 2009/2297, which apply to veterinary medicinal products irrespective of whether there is other legislation controlling a product: reg 2(4).

2 'Animal' means all animals other than man and includes birds, reptiles, fish, molluscs, crustacea and bees: SI 2009/2297 reg 2(2).

3 SI 2009/2297 reg 2(1).

4 SI 2009/2297 Sch 3 para 1(2). The Secretary of State may change the classification after the marketing authorisation has been granted: see Sch 3 para 1(3). As to marketing authorisations see PARA 34B.1.

5 SI 2009/2297 Sch 3 para 1(1). Specified products must be classified as Prescription Only Medicine--Veterinarian, and others must be classified as Prescription Only Medicine--Veterinarian or Prescription Only Medicine--Veterinarian, Pharmacist, Suitably Qualified Person: see Sch 3 para 1(4), (5). There are no restrictions on the importation of an authorised veterinary medicinal product in category Authorised Veterinary Medicine--General Sales List: reg 9(7).

6 SI 2009/2297 reg 3(1).

7 Ie licensed under the Animals (Scientific Procedure) Act 1986: see ANIMALS vol 2 (2008) PARA 875 et seq.

8 le granted under SI 2009/2297 Sch 4 para 9 (see PARA 34B.2): reg 3(2).

9 SI 2009/2297 reg 15(1). Further, Sch 1 and Sch 2 Pt 1 do not apply in relation to an inactivated autogenous vaccine that is (1) manufactured by a person and in premises authorised in accordance with Sch 2 Pt 2, on the instructions of a veterinary surgeon, from pathogens or antigens obtained from an animal; and (2) used for the treatment of other animals on the same site, animals intended to be sent to those premises, or animals on a site that receives animals from those premises: reg 15(2). As to manufacturing authorisations see PARA 34B.3.

10 le SI 2009/2297 Sch 6.

11 le aquarium fish, cage birds, ferrets, homing pigeons, rabbits, small rodents, terrarium animals: SI 2009/2297 Sch 6 para 1.

12 SI 2009/2297 Sch 6 para 2.

2. Supply and possession

Restrictions apply to the wholesale and retail supply of veterinary medicinal products¹. A veterinary surgeon who prescribes a veterinary medicinal product classified as Prescription Only Medicine--Veterinarian must first carry out a clinical assessment of the animal². Only suitably qualified persons may prescribe and supply veterinary medicinal products³. Veterinary surgeons, pharmacists and suitably qualified persons may import authorised veterinary medicinal products⁴.

It is an offence⁵ for any person to supply a veterinary medicinal product that has passed its expiry date⁶, to open the package (including the outer package) of a veterinary medicinal product before it has been supplied to the final user⁷, supply an authorised human medicinal product for administration to an animal⁸, or be in possession of a veterinary medicinal product which has been supplied to that person other than in accordance with the provisions governing its supply⁹.

1 See the Veterinary Medicines Regulations 2009, SI 2009/2297, Sch 3 paras 2, 3, Sch 5 paras 14-19, 21-28. For the meaning of 'veterinary medicinal product' see PARA 34A.1.

2 SI 2009/2297 Sch 3 para 4. As to the form of prescriptions, see Sch 3 para 6. For further provisions as to the supply of veterinary medicinal products by veterinary surgeons or pharmacists see Sch 3 paras 5, 7-12. For the meaning of 'animal' see PARA 34A.1 NOTE 2.

3 See SI 2009/2297 Sch 3 para 14.

4 SI 2009/2297 reg 9(5), (6). However, a suitably qualified person may only import those authorised veterinary medicinal products that that person is permitted to supply: reg 9(6). It is an offence to import a veterinary medicinal product authorised for use in the United Kingdom except in accordance with reg 9: reg 9(1).

5 As to offences see PARA 34D.6.

6 SI 2009/2297 reg 7(2).

7 SI 2009/2297 reg 7(3). However, it is not an offence to open such a package as permitted under Sch 3: reg 7(3). A wholesale dealer may break open any package, other than the immediate packaging, of a veterinary medicinal product (Sch 3 para 2(6)); a pharmacist may break open any package containing a veterinary medicinal product for the purposes of supply other than the immediate packaging of injectable products (Sch 3 para 10(5)); and a suitably qualified person may break open any package, other than the immediate packaging, of a veterinary medicinal product (Sch 3 para 14(9)).

8 SI 2009/2297 reg 7(4). However, this does not apply to a product supplied by a veterinary surgeon or supplied in accordance with a prescription from a veterinary surgeon that includes all the information specified by Sch 3 para 6 (see NOTE 2): reg 7(4).

9 le SI 2009/2297 Sch 3: reg 7(5).

3. Exports

It is an offence to export a veterinary medicinal product¹ for use in another member state² unless the veterinary medicinal product may be lawfully supplied or administered there³. If a veterinary medicinal product has been manufactured in accordance with a marketing authorisation⁴, or if a product without a marketing authorisation has been manufactured under a manufacturing authorisation⁵, and the product is intended for export outside the European Union, the Secretary of State must, at the request of the exporter or the competent authorities of the country of export, provide a certificate⁶ to that effect⁷. If the veterinary medicinal product is authorised in the United Kingdom, the Secretary of State must ensure that the exporter or the competent authorities of the third country has access to the summary of product characteristics⁸.

1 For the meaning of 'veterinary medicinal product' see PARA 34A.1.

2 For the meaning of 'member state' see PARA 34B.1 NOTE 4.

3 Veterinary Medicines Regulations 2009, SI 2009/2297, reg 31(1).

4 As to marketing authorisations see PARA 34B.1.

5 As to manufacturing authorisations see PARA 34B.3.

6 When issuing the certificate the Secretary of State must take account of the model certificates issued by the World Health Organization: SI 2009/2297 reg 31(3).

7 SI 2009/2297 reg 31(2).

8 SI 2009/2297 reg 31(4).

UPDATE

34-41 Veterinary Medical Products

SI 1994/2986, SI 1994/2987, SI 1994/3142, SI 1997/322, SI 1998/1046, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. As to marketing and other authorisations see now the Veterinary Medicines Regulations 2009, SI 2009/2297; and PARAS 34A-34D.

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34B. Veterinary medicinal products: authorisations.

1. Marketing authorisations

An application for a marketing authorisation for a veterinary medicinal product¹ must be made to the Secretary of State², and must include specified information about the product³. A marketing authorisation may be granted only to an applicant established in a member state⁴. Provision is made as to the grant of marketing authorisations⁵ variations of marketing authorisations⁶, suspension and revocation of marketing authorisations⁷, labelling and package leaflets⁸, pharmacovigilance⁹ and homeopathic veterinary medicinal products¹⁰. A holder of a marketing authorisation for a veterinary medicinal product may import that veterinary medicinal product¹¹.

It is an offence to place a veterinary medicinal product on the market unless that product has been granted a marketing authorisation by the Secretary of State or the European Medicines Agency¹². Any person who certifies data in relation to an application for a marketing authorisation or in relation to an existing marketing authorisation and who knows that those data are false, or does not believe that they are accurate, is guilty of an offence¹³. Further, the holder of a marketing authorisation for a veterinary medicinal product is guilty of an offence if the finished product supplied by the holder or the manufacturer is not completely in accordance with the marketing authorisation¹⁴.

1 For the meaning of 'veterinary medicinal product' see PARA 34A.1.

2 Veterinary Medicines Regulations 2009, SI 2009/2297, Sch 1 para 1.

3 See SI 2009/2297 Sch 1 paras 2, 3. As to derogations from certain of the requirement to provide information, see Sch 1 Pt 2 (paras 6-16).

4 SI 2009/2297 Sch 1 para 18. For the purposes of SI 2009/2297, a reference to a member state is a reference to a member state of the European Union and Norway, Iceland and Liechtenstein: reg 2(3). As to the mutual recognition of marketing authorisations between member states, and applications for a marketing authorisation in more than one member state, see Sch 1 Pt 6 (paras 42-44).

5 SI 2009/2297 Sch 1 Pt 3 (paras 17-32).

6 SI 2009/2297 Sch 1 Pt 4 (paras 33-37).

7 SI 2009/2297 Sch 1 Pt 5 (paras 38-41).

8 SI 2009/2297 Sch 1 Pt 7 (paras 45-54), Sch 5 paras 11-13.

9 SI 2009/2297 Sch 1 Pt 8 (paras 55-61).

10 SI 2009/2297 Sch 1 Pt 9 (paras 62-67).

11 SI 2009/2297 reg 9(2). It is an offence to import a veterinary medicinal product authorised for use in the United Kingdom except in accordance with reg 9: reg 9(1). As to offences see PARA 34D.6.

12 SI 2009/2297 reg 4(1). The European Medicines Agency was established by European Parliament and EC Council Regulation 726/2004. As to fees relating to marketing authorisations see SI 2009/2297 Sch 7 Pt 2 (paras 7-27). See generally Sch 7 Pt 6 (paras 46-64).

13 SI 2009/2297 reg 4(2).

14 SI 2009/2297 reg 6.

2. Administration

It is an offence¹ to administer a veterinary medicinal product² to an animal³ unless the product has a marketing authorisation⁴ authorising its administration in the United Kingdom, and the administration is in accordance with that marketing authorisation⁵, or it is administered in accordance with special provisions outside the terms of a marketing authorisation⁶. If there is no authorised veterinary medicinal product in the United Kingdom for a condition the veterinary surgeon responsible for the animal may, in particular to avoid unacceptable suffering, treat the animal concerned with the following ('the cascade'), cascaded in the following order (1) a veterinary medicinal product authorised in the United Kingdom for use with another animal species, or for another condition in the same species⁷; (2) if and only if there is no such product that is suitable, either (a) a human medicinal product authorised in the United Kingdom; or (b) a veterinary medicinal product not authorised in the United Kingdom but authorised in another member state⁸ for use with any animal species⁹; or (3) if and only if there is no such product that is suitable, a veterinary medicinal product prepared extemporaneously by a pharmacist, a veterinary surgeon or a person holding a manufacturing authorisation¹⁰ authorising the manufacture of that type of product¹¹.

1 As to offences see PARA 34D.6.

2 For the meaning of 'veterinary medicinal product' see PARA 34A.1.

3 For the meaning of 'animal' see PARA 34A.1 NOTE 2.

4 As to marketing authorisations see PARA 34B.1.

5 SI 2009/2297 reg 8(a).

6 See SI 2009/2297 reg 8(b), Schs 4, 6.

7 See SI 2009/2297 Sch 4 para 1(2)(a).

8 For the meaning of 'member state' see PARA 34B.1 NOTE 4.

9 See SI 2009/2297 Sch 4 para 1(2)(b).

10 As to manufacturing authorisations see PARA 34B.3.

11 See SI 2009/2297 Sch 4 para 1(2)(c). As to further provisions as to the administration of veterinary medicinal product outside the terms of a marketing authorisation, see Sch 4 paras 1(3), (4), 2-9.

3. Manufacture and manufacturing authorisations

An application for a manufacturing authorisation must be made to the Secretary of State¹. A manufacturing authorisation must specify (1) the types of veterinary medicinal products² and pharmaceutical forms that may be manufactured or imported; (2) the place where they are to be manufactured or controlled; (3) the name and address of the person holding the authorisation; (4) the address of the premises to which it relates; (5) the name of all qualified person nominated to act³. Additionally, it may specify that different activities must be carried out in different premises or parts of premises, and may require the holder of to restrict access to premises or parts of premises to persons carrying out activities there⁴. Further provision is made in relation to manufacturing authorisations⁵, in particular, in relation to authorisation of manufacturers of autogenous vaccines⁶, in relation to authorisation of blood banks⁷, in relation to authorisation to manufacture products for administration under the cascade⁸, and in relation

to authorisation of equine stem cell centres⁹. A holder of a manufacturing authorisation may import a veterinary medicinal product to which that authorisation relates¹⁰.

The holder of a marketing authorisation¹¹ must ensure that every stage in the manufacture¹² of the veterinary medicinal product is carried out by the manufacturer specified in the marketing authorisation, and failure to do so is an offence¹³.

1 Veterinary Medicines Regulations 2009, SI 2009/2297, Sch 2 para 1. The Secretary of State must grant a manufacturing authorisation where certain conditions are fulfilled: Sch 2 para 3. As to fees relating to manufacturing authorisations see Sch 7 Pt 2 (paras 7-27). Also, see generally Sch 7 Pt 6 (paras 46-64).

2 For the meaning of 'veterinary medicinal product' see PARA 34A.1.

3 SI 2009/2297 Sch 2 para 4(1).

4 SI 2009/2297 Sch 2 para 4(2).

5 See generally SI 2009/2297 Sch 2 Pt 1 (paras 1-13). See also reg 15(2), (3).

6 SI 2009/2297 Sch 2 Pt 2 (paras 14-19).

7 SI 2009/2297 Sch 2 Pt 3 (paras 20-24).

8 SI 2009/2297 Sch 2 Pt 4 (paras 25-29).

9 SI 2009/2297 Sch 2 Pt 5 (paras 30-34).

10 SI 2009/2297 reg 9(3). It is an offence to import a veterinary medicinal product authorised for use in the United Kingdom except in accordance with reg 9: reg 9(1). As to offences see PARA 34D.6.

11 As to marketing authorisations see PARA 34B.1.

12 'Manufacture' includes any part of the manufacture of a veterinary medicinal product until the finished product is ready for sale in its final form as specified in the marketing authorisation but does not include the manufacture of an ingredient or breaking open a veterinary medicinal product: SI 2009/2297 reg 5(3).

13 SI 2009/2297 reg 5(1). The manufacturer must, if the manufacture is carried out in the United Kingdom, hold a manufacturing authorisation for that type of product granted by the Secretary of State: reg 5(1). It is also an offence to incorporate a veterinary medicinal product into a premixture or into feedingstuffs, or sprinkle it on to feedingstuffs, unless certain requirements are met: see Sch 5 paras 6-9.

4. Wholesale dealer's authorisations

An application for a wholesale dealer's authorisation must be made to the Secretary of State¹. The wholesale dealer's authorisation specifies (1) the types of veterinary medicinal products² and pharmaceutical forms that may be dealt in; (2) the place where they are to be stored; (3) the name and address of the person holding the authorisation; (4) the address of the premises to which it relates; (5) the name of the qualified person nominated to act under the guidelines on good distribution practice for human use³. An authorisation may cover more than one site⁴, and lapses if the holder does not deal in veterinary medicinal products for five years⁵. Further provision is made as to the suspension, variation and revocation of authorisations⁶, and duties of the holder of an authorisation⁷. An authorised wholesale dealer may import a veterinary medicinal product if (a) the authorisation covers the product⁸; and (b) the dealer has notified the holder of the marketing authorisation⁹ in writing before importation¹⁰.

It is an offence to buy a veterinary medicinal product, other than by retail or for the purposes of retail supply¹¹, unless the buyer has a wholesale dealer's authorisation granted by the Secretary of State¹².

It is an offence to supply sheep dip by retail, other than with prescribed certification¹³.

- 1 See Veterinary Medicines Regulations 2009, SI 2009/2297, Sch 3 para 16. The Secretary of State must grant a wholesale dealer's authorisation where certain conditions are fulfilled: Sch 3 para 18. As to fees relating to a wholesale dealer's authorisation see Sch 7 Pt 4 (paras 39-42). Also, see generally Sch 7 Pt 6 (paras 46-64).
- 2 For the meaning of 'veterinary medicinal product' see PARA 34A.1.
- 3 SI 2009/2297 Sch 3 para 19(1).
- 4 SI 2009/2297 Sch 3 para 19(2).
- 5 SI 2009/2297 Sch 3 para 19(3).
- 6 See SI 2009/2297 Sch 3 para 20.
- 7 See SI 2009/2297 Sch 3 para 21.
- 8 SI 2009/2297 reg 9(4)(a).
- 9 As to marketing authorisations see PARA 34B.1.
- 10 SI 2009/2297 reg 9(4)(b). It is an offence to import a veterinary medicinal product authorised for use in the United Kingdom except in accordance with reg 9: reg 9(1). As to offences see PARA 34D.6.
- 11 I.e. in accordance with SI 2009/2297 Sch 3.
- 12 SI 2009/2297 reg 13.
- 13 See SI 2009/2297 Sch 3 Pt 3 (paras 22, 23).

5. Advertising

It is an offence¹ to (1) advertise a veterinary medicinal product² if the advertisement is misleading or contains any medicinal claim that is not in the summary of product characteristics³; (2) advertise an authorised human medicinal product for administration to animals⁴, including sending a price list of or including authorised human medicinal products to a veterinary surgeon or veterinary practice⁵; (3) advertise a veterinary medicinal product that is available on veterinary prescription only, or contains psychotropic drugs or narcotics⁶.

In proceedings for an offence⁷ relating to advertising, it is a defence for the person charged to prove that that person's business is to publish or arrange for the publication of advertisements, and that the advertisement was received in the ordinary course of business and the person charged did not know and had no reason to suspect that its publication would amount to such an offence⁸.

- 1 As to offences see PARA 34D.6.
- 2 For the meaning of 'veterinary medicinal product' see PARA 34A.1.
- 3 Veterinary Medicines Regulations 2009, SI 2009/2297, reg 10(1).
- 4 For the meaning of 'animal' see PARA 34A.1 NOTE 2.
- 5 SI 2009/2297 reg 10(2). However, this does not apply to the holder of a wholesale dealer's authorisation who supplies a list of human medicines, together with prices, to a veterinary surgeon for use under the cascade (see PARA 34B.2) provided that (1) the list is sent following a request from the veterinary surgeon to whom it is sent; and (2) the list states clearly that the product does not have a marketing authorisation as a veterinary medicinal product, and may only be administered under the cascade: reg 10(3). As to wholesale dealer's authorisations see PARA 34B.4. As to marketing authorisations see PARA 34B.1.
- 6 SI 2009/2297 reg 11(1). In the case of a product containing psychotropic drugs or narcotics, this does not apply to advertisements aimed at veterinary surgeons: reg 11(2). In the case of Prescription Only Medicine--Veterinarian medicines, this does not apply to price lists, or to advertisements aimed at veterinary surgeons, veterinary nurses, pharmacists or professional keepers of animals: reg 11(3). In the case of Prescription Only Medicine--Veterinarian, Pharmacist, Suitably Qualified Person medicines, this does not apply to price lists, or to

advertisements aimed at (1) veterinary surgeons; (2) pharmacists; (3) suitably qualified persons registered in accordance with Sch 3 para 14; (4) other veterinary health care professionals; (5) professional keepers of animals; or (6) owners or keepers of horses: reg 11(4). As to the classes of veterinary medicinal products see PARA 34A.1.

7 le under SI 2009/2297.

8 SI 2009/2297 reg 12.

6. Unauthorised medicinal veterinary products

It is an offence¹ to import an unauthorised² veterinary medicinal product³ except in accordance with the following provisions⁴. A holder of a marketing authorisation⁵ may import an unauthorised veterinary medicinal product if it is for the purpose of the manufacture of a veterinary medicinal product for which the importer holds the marketing authorisation⁶. A holder of a manufacturing authorisation⁷ may import an unauthorised veterinary medicinal product if it is for the manufacture of a veterinary medicinal product that the importer is permitted to manufacture⁸. A holder of a wholesale dealer's authorisation⁹ may import an unauthorised veterinary medicinal product for the purposes of re-export¹⁰. A veterinary surgeon may import an unauthorised veterinary medicinal product that is authorised in another member state¹¹ if it is for the purpose of administration by that veterinary surgeon or under the veterinary surgeon's responsibility under the cascade¹² or administration in exceptional circumstances¹³. A wholesale dealer or a pharmacist may import an unauthorised veterinary medicinal product for the purpose of storing it pending administration by a veterinary surgeon under the cascade or administration in exceptional circumstances if (1) the veterinary medicinal product is authorised in another member state or a third country; (2) the Secretary of State has issued a certificate certifying that (a) the disease or condition is such that the veterinary medicinal product is likely to be needed as a matter of urgency for the treatment of an animal¹⁴; (b) delay in administering the product will seriously affect the health or welfare of the animal; and (c) there is no suitable veterinary medicinal product authorised in the United Kingdom; and (3) in the case of a wholesale dealer, the product is within the terms of the authorisation¹⁵.

It is an offence to be in possession of an unauthorised veterinary medicinal product¹⁶, but it is not an offence to be in possession of a product imported in accordance with a certificate granted by the Secretary of State¹⁷ or prescribed by a veterinary surgeon under the cascade¹⁸. Further, the offence does not apply to a holder of a manufacturing authorisation if the possession is for export, the holder of a wholesale dealer's authorisation if the possession is for export or re-export, nor to holders of a manufacturer's authorisation or marketing authorisation if the intention is to manufacture a veterinary medicinal product¹⁹. Further, a veterinary surgeon who practises in both the United Kingdom and another member state may hold veterinary medicinal products authorised in the other member state provided that the amount held does not exceed the amount expected to be used in that member state²⁰. It is a defence for a person to prove that the product was for the purposes of research or development of a veterinary medicinal product²¹. A veterinary surgeon may possession of an authorised human medicinal product intended for administration to animals under the cascade, but commits an offence if the amount possessed exceeds the amount expected to be used under the cascade²².

It is an offence to supply an unauthorised veterinary medicinal product²³. However, an offence does not apply to a product prescribed by a veterinary surgeon under the cascade²⁴ or a product supplied in accordance with a certificate granted by the Secretary of State²⁵.

1 As to offences see PARA 34D.6.

2 The holder of an animal test certificate granted under the Veterinary Medicines Regulations 2009, SI 2009/2297, Sch 4 para 9 may import anything specified in the animal test certificate in accordance with the conditions in that certificate: reg 25(7). The Secretary of State may authorise in writing the importation of any

product or substance for use under a licence granted under the Animals (Scientific Procedures) Act 1986 (see ANIMALS vol 2 (2008) PARA 875 et seq): reg 25(8).

3 For the meaning of 'veterinary medicinal product' see PARA 34A.1.

4 SI 2009/2297 reg 25(1).

5 As to marketing authorisations see PARA 34B.1.

6 SI 2009/2297 reg 25(2).

7 As to manufacturing authorisations see PARA 34B.3.

8 SI 2009/2297 reg 25(3).

9 As to wholesale dealer's authorisations see PARA 34B.4.

10 SI 2009/2297 reg 25(4).

11 For the meaning of 'member state' see PARA 34B.1 NOTE 4.

12 As to the cascade see PARA 34B.2.

13 Ie in accordance with SI 2009/2297 Sch 4: reg 25(5). The import must be in accordance with the appropriate certificate granted by the Secretary of State, and the product may be imported by the veterinary surgeon personally or by using a wholesale dealer or pharmacist as an agent: reg 25(5).

14 For the meaning of 'animal' see PARA 34A.1 NOTE 2.

15 SI 2009/2297 reg 25(6). Any such import must be in accordance with Sch 4.

16 SI 2009/2297 reg 26(1).

17 Ie under SI 2009/2297: reg 26(2)(a).

18 SI 2009/2297 reg 26(2)(b).

19 SI 2009/2297 reg 26(2)(c)-(e).

20 SI 2009/2297 reg 26(3).

21 SI 2009/2297 reg 26(4).

22 SI 2009/2297 reg 26(5).

23 SI 2009/2297 reg 27(1). However, it is a defence for a person charged under reg 27(1) to prove that the supply was for the purposes of research or development of a veterinary medicinal product: reg 27(3).

24 SI 2009/2297 reg 27(2)(a).

25 SI 2009/2297 reg 27(2)(b).

UPDATE

34-41 Veterinary Medical Products

SI 1994/2986, SI 1994/2987, SI 1994/3142, SI 1997/322, SI 1998/1046, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. As to marketing and other authorisations see now the Veterinary Medicines Regulations 2009, SI 2009/2297; and PARAS 34A-34D.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(3) MARKETING AUTHORISATIONS/(iv) Veterinary Medicinal Products/A. MARKETING AUTHORISATIONS/34C. Veterinary medicinal products: records.

34C. Veterinary medicinal products: records.

1. Food-producing animals

The keeper of a food-producing animal¹ must keep proof of purchase or other form of acquisition of all veterinary medicinal products² acquired for the animal³. A veterinary surgeon who administers a veterinary medicinal product to a food-producing animal must either enter the following information personally in the keeper's records or give it to the keeper in writing (in which case the keeper must enter the following into those records): (1) the name of the veterinary surgeon; (2) the name of the product and the batch number; (3) the date of administration of the product; (4) the amount of product administered; (5) the identification of the animals treated; and (6) the withdrawal period⁴. When a veterinary medicinal product is bought or otherwise acquired for a food-producing animal the keeper must, at the time, record: (a) the name of the product and the batch number; (b) the date of acquisition; (c) the quantity acquired; and (d) the name and address of the supplier⁵.

The keeper must retain the documentation on the acquisition of a veterinary medical product and the record for at least five years following the administration or other disposal of the product, irrespective of whether or not the animal concerned is no longer in that keeper's possession or have been slaughtered or have died during that period⁶.

A veterinary surgeon administering a veterinary medicinal product to food-producing animals under the cascade⁷, or permitting another person to administer it under that veterinary surgeon's responsibility, must, as soon as is reasonably practicable, record: (1) the date of examination of the animals; (2) the name and address of the owner; (3) the identification and number of animals treated; (4) the result of the veterinary surgeon's clinical assessment; (5) the trade name of the product if there is one; (6) the manufacturer's batch number shown on the product if there is one; (7) the name and quantity of the active substances; (8) the doses administered or supplied; (9) the duration of treatment; and (10) the withdrawal period⁸.

Failure to comply with any of the requirements relating to record keeping⁹ is an offence¹⁰.

1 For the meaning of 'animal' see PARA 34A.1 NOTE 2.

2 For the meaning of 'veterinary medicinal product' see PARA 34A.1.

3 Ie in accordance with the Veterinary Medicines Regulations 2009, SI 2009/2297, reg 17(1).

4 SI 2009/2297 reg 18(1).

5 SI 2009/2297 reg 19(1).

6 SI 2009/2297 reg 20(1).

7 As to the cascade see PARA 34B.2.

8 Ie under SI 2009/2297 reg 24(1). The veterinary surgeon must keep the record for at least five years: reg 24(1). Additional record keeping requirements are set out in Sch 5 para 10.

9 Ie those set out in SI 2009/2297 regs 17, 18, 19, 20 and 24.

10 SI 2009/2297 regs 17(2), 18(2), 19(2), 20(2), 24(2). As to offences see PARA 34D.6.

2. Holders of manufacturing authorisations and wholesale dealer's authorisations

A holder of a manufacturing authorisation¹ must, as soon as is reasonably practicable, make a record of each batch of veterinary medicinal product² manufactured, assembled or supplied, which must include (1) the name of the product; (2) the quantity manufactured, assembled or supplied; (3) the date of manufacture, assembly or supply; (4) the batch number and expiry date; (5) in the case of supply, the name and address of the recipient³. The holder must also keep with the record all certification provided by the qualified person (manufacturing) in relation to that batch⁴, and keep all records and certificates for at least five years from the date the veterinary medicinal product is placed on the market⁵.

A holder of a wholesale dealer's authorisation must record the following as soon as is reasonably practicable after each incoming or outgoing transaction (including disposals) relating to a veterinary medicinal product: (a) the date and nature of the transaction; (b) the name of the veterinary medicinal product; (c) the manufacturer's batch number; (d) the expiry date; (e) the quantity; and (f) the name and address of the supplier or recipient⁶.

Failure to comply with any of the requirements relating to record keeping⁷ is an offence⁸.

1 As to manufacturing authorisations see PARA 34B.3.

2 For the meaning of 'veterinary medicinal product' see PARA 34A.1.

3 Veterinary Medicines Regulations 2009, SI 2009/2297, reg 21(1).

4 SI 2009/2297 reg 21(2).

5 SI 2009/2297 reg 21(3).

6 SI 2009/2297 reg 22(1). The holder must keep the records for at least three years: reg 22(1). Additional record keeping requirements are set out in Sch 5 para 10.

7 I.e. those in SI 2009/2297 regs 21 and 22.

8 SI 2009/2297 regs 21(4), 22(2). As to offences see PARA 34D.6.

3. Products supplied on prescription

Any person permitted¹ to supply veterinary medicinal products² classified as Prescription Only Medicine--Veterinarian or Prescription Only Medicine--Veterinarian, Pharmacist, Suitably Qualified Person³ who receives or supplies any such veterinary medicinal product must keep all documents relating to the transaction⁴. These documents must show: (1) the date; (2) the name of the veterinary medicinal product; (3) the batch number (except that, in the case of a product for a non-food-producing animal, this need only be recorded either on the date of receipt or the date a supply veterinary medicinal product is first supplied); (4) the quantity; (5) the name and address of the supplier or recipient; (6) if there is a written prescription, the name and address of the person who wrote the prescription and a copy of the prescription⁵. Alternatively, the person may make a record of all the information⁶, provided that this is done as soon as is reasonably practicable following the transaction⁷. The documentation and records must be kept for at least five years⁸. Failure to comply with any of the requirements relating to record keeping⁹ is an offence¹⁰.

1 I.e. under the Veterinary Medicines Regulations 2009, SI 2009/2297.

2 For the meaning of 'veterinary medicinal product' see PARA 34A.1.

- 3 As to the classification of veterinary medicinal products see PARA 34A.1.
- 4 SI 2009/2297 reg 23(1).
- 5 SI 2009/2297 reg 23(1)(a)-(f). If the documents do not include this information that person must make a record of the missing information as soon as is reasonably practicable following the transaction: reg 23(2).
- 6 Ie the information required by SI 2009/2297 reg 23(1), (2).
- 7 SI 2009/2297 reg 23(3).
- 8 SI 2009/2297 reg 23(4). Additional record keeping requirements are set out in Sch 5 para 10.
- 9 Ie those set out in SI 2009/2297 reg 23.
- 10 SI 2009/2297 reg 23(5). As to offences see PARA 34D.6.

UPDATE

34-41 Veterinary Medical Products

SI 1994/2986, SI 1994/2987, SI 1994/3142, SI 1997/322, SI 1998/1046, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. As to marketing and other authorisations see now the Veterinary Medicines Regulations 2009, SI 2009/2297; and PARAS 34A-34D.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(3) MARKETING AUTHORISATIONS/(iv) Veterinary Medicinal Products/A. MARKETING AUTHORISATIONS/34D. Veterinary medicinal products: enforcement and offences.

34D. Veterinary medicinal products: enforcement and offences.

1. General powers

For certain purposes¹, the Secretary of State must appoint inspectors². An inspector entering premises³ may (1) inspect the premises, and any plant, machinery or equipment⁴; (2) search the premises⁵; (3) take samples⁶; (4) seize any computers and associated equipment⁷; (5) seize any veterinary medicinal product, anything purporting to be a veterinary medicinal product, or any additive, if it is not authorised in the United Kingdom⁸; (6) seize any premixture or feedingstuff that contains a veterinary medicinal product or additive that is not authorised in the United Kingdom⁹; (7) seize any veterinary medicinal product, anything purporting to be a veterinary medicinal product, any additive¹⁰, any premixture or any feedingstuff if (a) it has not been lawfully supplied¹¹; (b) it has been stored in a way that affects its safety, quality or efficacy¹²; (c) it is sold or offered for sale by a person not permitted to supply it¹³; (8) carry out any inquiries, examinations and tests¹⁴; (9) have access to, and inspect and copy or seize any documents or records, in whatever form they are held¹⁵; (10) have access to, inspect and check the operation of any computer and any associated apparatus or material which is or has been in use in connection with the records¹⁶. In relation to a pharmacy, all the enforcement powers¹⁷ of an inspector may also be exercised by an officer of the Royal Pharmaceutical Society of Great Britain appointed for the purpose¹⁸. Provision is made in relation to the enforcement of European legislation concerning certain feedingstuffs and feed additives¹⁹.

1 Ie enforcement of the Veterinary Medicines Regulations 2009, SI 2009/2297.

2 SI 2009/2297 reg 33.

3 'Premises' includes any place, vehicle, trailer, container, stall, moveable structure, ship or aircraft: SI 2009/2297 reg 34(1).

4 SI 2009/2297 reg 35(1)(a).

5 SI 2009/2297 reg 35(1)(b).

6 SI 2009/2297 reg 35(1)(c).

7 SI 2009/2297 reg 35(1)(d).

8 Ie any additive to which SI 2009/2297 Sch 5 applies: reg 35(1)(e).

9 Ie any additive to which SI 2009/2297 Sch 5 applies: reg 35(1)(f).

10 Ie any additive to which SI 2009/2297 Sch 5 applies: reg 35(1)(g).

11 Ie in accordance with SI 2009/2297: reg 35(1)(g)(i).

12 SI 2009/2297 reg 35(1)(g)(ii).

13 Ie under SI 2009/2297: reg 35(1)(g)(iii).

14 SI 2009/2297 reg 35(1)(h).

15 SI 2009/2297 reg 35(1)(i).

16 SI 2009/2297 reg 35(1)(j). For this purpose the inspector may require any person having charge of, or otherwise concerned with the operation of, the computer, apparatus or material to afford such assistance as may reasonably be required and, where a record is kept by means of a computer, may require the records to be produced in a form in which they may be taken away: reg 35(1)(j). An officer of any local authority who has entered premises exercising any statutory power of entry for the purposes of enforcing any legislation relating to food hygiene, feed hygiene or animal health, may inspect any records made under SI 2009/2297, in whatever form they are held, relating to food-producing animals and may remove them to enable them to be copied: reg 35(2).

17 Ie under SI 2009/2297.

18 SI 2009/2297 reg 36. As to the Royal Pharmaceutical Society of Great Britain see PARAS 881-887.

19 See SI 2009/2297 Sch 5 paras 2-5.

2. Powers of entry

An inspector may, on producing a duly authenticated authorisation if required, enter any premises¹ at any reasonable hour for the purpose of ensuring compliance². The inspector may be accompanied by such other persons as the inspector considers necessary, and any representative of the European Commission acting for the purpose of the enforcement of a Community obligation³. Admission to any premises used only as a private dwellinghouse may not be demanded as of right unless 24 hours notice of the intended entry has been given to the occupier, or the entry is in accordance with a warrant⁴.

If a justice of the peace, on sworn information in writing, is satisfied that there are reasonable grounds for entry into any premises for the purposes of the enforcement, and either (1) admission has been refused, or a refusal is expected, and (in either case) that notice to apply for a warrant has been given to the occupier; (2) asking for admission, or the giving of such a notice, would defeat the object of the entry; (3) the case is one of urgency; or (4) the premises are unoccupied or the occupier is temporarily absent, the justice may by signed warrant authorise the inspector to enter the premises, if need be by reasonable force⁵. An inspector who enters any unoccupied premises must leave them as effectively secured against unauthorised entry as they were before entry⁶. An inspector may enter the premises of manufacturers of active substances used as starting materials for veterinary medicinal products⁷, and the premises of the marketing authorisation holder⁸. In addition, an inspector may carry out an inspection at the request of another member state⁹, the European Commission or the European Medicines Agency¹⁰.

1 For the meaning of 'premises' see 34D.1 NOTE 3.

2 Ie compliance with the Veterinary Medicines Regulations 2009, SI 2009/2297: reg 34(1).

3 SI 2009/2297 reg 34(2).

4 Ie a warrant granted under SI 2009/2297 reg 34: reg 34(3).

5 SI 2009/2297 reg 34(4). Such a warrant continue in force for one month: reg 34(5).

6 SI 2009/2297 reg 34(6).

7 For the meaning of 'veterinary medicinal product' see PARA 34A.1.

8 SI 2009/2297 reg 34(7). As to marketing authorisations see PARA 34B.1.

9 For the meaning of 'member state' see PARA 34B.1 NOTE 4.

10 SI 2009/2297 reg 34(8).

3. Obstruction

Any person who (1) intentionally obstructs any person acting in the execution of that person's duties¹; (2) without reasonable cause, fails to give to any person acting in the execution of those duties any assistance or information which that person may reasonably require²; (3) furnishes to any person acting in the execution of his duties³ any information knowing it to be false or misleading⁴; or (4) fails to produce a record when required to do so to any person acting in the execution of that person's duties⁵, is guilty of an offence⁶.

1 Ie under the Veterinary Medicines Regulations 2009, SI 2009/2297: reg 37(1)(a).

2 Ie under SI 2009/2297: reg 37(1)(b).

3 Ie under SI 2009/2297.

4 SI 2009/2297 reg 37(1)(c).

5 Ie under SI 2009/2297: reg 37(1)(d).

6 SI 2009/2297 reg 37(1). As to offences see PARA 34D.6.

4. Improvement notices

An inspector who has reasonable grounds for believing that any person is failing to comply with that person's duties¹ may serve an improvement notice on that person². An improvement notice must (1) state the inspector's grounds for believing this³; (2) specify the matters which constitute the failure to comply⁴; (3) specify the measures which, in the inspector's opinion, the person must take in order to secure compliance⁵; and (4) require the person to take those measures, or measures which are at least equivalent to them, within the period specified in the notice⁶. It must also state the right of appeal and period within which such an appeal may be brought⁷. It is an offence⁸ to fail to comply with an improvement notice⁹.

Any person who is aggrieved by an improvement notice may appeal by way of complaint to a magistrates' court¹⁰. A court may suspend an improvement notice pending an appeal¹¹. On such an appeal, the court may either cancel or affirm the notice, with or without modifications¹².

1 Ie under the Veterinary Medicines Regulations 2009, SI 2009/2297.

2 SI 2009/2297 reg 38(1). The Secretary of State must publicise all improvement notices issued and the suspension or revocation of anything issued under SI 2009/2297, and may do so in such manner as the Secretary of State sees fit: reg 42(1).

3 SI 2009/2297 reg 38(1)(a).

4 SI 2009/2297 reg 38(1)(b).

5 SI 2009/2297 reg 38(1)(c).

6 SI 2009/2297 reg 38(1)(d). The period so specified is not to be less than 14 days: reg 38(1)(d).

7 SI 2009/2297 reg 39(5).

8 As to offences see PARA 34D.6.

9 SI 2009/2297 reg 38(2).

10 SI 2009/2297 reg 39(1), (2). The Magistrates' Courts Act 1980 (see generally COURTS; MAGISTRATES) is to apply to the proceedings: SI 2009/2297 reg 39(2). The period within which an appeal may be brought is 28 days or the period specified in the improvement notice, whichever ends the earlier: reg 39(4).

11 SI 2009/2297 reg 39(6).

12 SI 2009/2297 reg 40.

5. Seizure notices

When seizing anything¹, an inspector must serve on the person appearing to be in charge of the seized product a seizure notice giving the grounds for seizing the product, and informing that person's of that person's rights to make a claim, and the address for the service of the claim². An inspector who is not able to remove the products seized immediately may mark them in any way, and serve a notice on the person in charge of the products identifying them, and prohibiting the removal of the products from the premises until they are collected by an inspector³. The person on whom the seizure notice was served or the owner of the seized product may, within 28 days of seizure, notify any claim that the product was not liable to seizure to the Secretary of State at the address specified in the seizure notice, setting out the grounds in full⁴. If a notification of a claim is received within 28 days, then, unless the product seized is being held for the purposes of pending or contemplated criminal proceedings, or for a criminal investigation, the Secretary of State must either return the product or take proceedings for an order for the confirmation of the seizure notice and the destruction of the veterinary medicinal product⁵ in a magistrates' court, and if the court confirms the notice it must order its destruction⁶.

1 Ie under the Veterinary Medicines Regulations 2009, SI 2009/2297.

2 SI 2009/2297 reg 41(1), (2). The Secretary of State must publicise all seizure notices (other than a seizure notice issued to a common carrier who does not own the seized goods) issued and the suspension or revocation of anything issued under SI 2009/2297, and may do so in such manner as the Secretary of State sees fit: reg 42(1), (2).

3 SI 2009/2297 reg 41(1), (3). Any person other than an inspector who removes products identified under reg 41(3) from the premises is guilty of an offence: reg 41(3). As to offences see PARA 34D.6.

4 SI 2009/2297 reg 41(4). If a notification of a claim is not received within 28 days, the Secretary of State may destroy the product: reg 41(5). The person on whom the seizure notice was served is liable for the costs of transport, storage for up to 28 days and destruction of the product seized unless a claim is made to a court and the court directs otherwise: reg 41(9).

5 For the meaning of 'veterinary medicinal product' see PARA 34A.1.

6 SI 2009/2297 reg 41(6). The procedure in a magistrates' court under reg 41 is by way of complaint, and the Magistrates' Courts Act 1980 applies to the proceedings: SI 2009/2297 reg 41(7). See generally MAGISTRATES.

6. Offences

A person guilty of an offence¹ is liable (1) on summary conviction, to a fine not exceeding the statutory maximum² or to imprisonment for a term not exceeding three months or both³; or (2) on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or both⁴. Where a body corporate is guilty of such an offence, and that offence is proved to have been committed with the consent or connivance of, or to have been attributable to any neglect on the part of (a) a qualified person⁵; (b) any director⁶, manager, secretary or other similar person of the body corporate; or (c) any person who was purporting to act in any such capacity, then that person, as well as the body corporate, is guilty of the offence⁷.

1 Ie under the Veterinary Medicines Regulations 2009, SI 2009/2297.

2 As to the statutory maximum see PARA 32.

3 SI 2009/2297 reg 43(1)(a).

4 SI 2009/2297 reg 43(1)(b).

5 le appointed as such for the purposes of SI 2009/2297.

6 'Director', in relation to a body corporate whose affairs are managed by its members, means a member of the body corporate: SI 2009/2297 reg 43(3).

7 SI 2009/2297 reg 43(2). Where an offence that has been committed by a Scottish partnership is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, a partner, the partner as well as the partnership is guilty of the offence: reg 43(4).

UPDATE

34-41 Veterinary Medical Products

SI 1994/2986, SI 1994/2987, SI 1994/3142, SI 1997/322, SI 1998/1046, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. As to marketing and other authorisations see now the Veterinary Medicines Regulations 2009, SI 2009/2297; and PARAS 34A-34D.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(3) MARKETING AUTHORISATIONS/(iv) Veterinary Medicinal Products/A. MARKETING AUTHORISATIONS/35. Authorisations.

35. Authorisations.

Every application for a marketing authorisation to the ministers¹ must be in writing², in the English language and signed by the applicant³. The applicant must supply four copies of each application, and a further 22 copies if the ministers so direct⁴. The ministers must consider an application for, and where appropriate grant, a marketing authorisation for a veterinary medicinal product⁵ in accordance with the appropriate requirements⁶.

The ministers may, on the application of the holder of a marketing authorisation, vary the conditions relating to the authorisation in accordance with any proposals contained in the application, if they are satisfied that the variation will not adversely affect the safety, quality or efficacy of a product of any description to which the authorisation relates⁷. The ministers may⁸ suspend or revoke a marketing authorisation⁹.

Every application for renewal of a marketing authorisation by the ministers must be made to them in accordance with specified requirements¹⁰. Where an application for the renewal of a marketing authorisation has been made the authorisation remains in force pending the decision of the ministers¹¹.

1 Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 4(1) (reg 4, Schs 1, 2 substituted by SI 2002/269). As to marketing authorisations see PARA 34 ante. For the meaning of 'the ministers' see PARA 3 note 3 ante; definition applied by the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 18(2).

2 For the meaning of 'writing' see PARA 21 note 6 ante; definition applied by ibid reg 18(2).

3 Ibid reg 4(2) (as substituted: see note 1 supra). The application: (1) must be as specified in EC Parliament and Council Directive 2001/82 (OJ L311, 28.11.2001, p 1) arts 12-15 (or, in the case of an application for the authorisation of a product already authorised in another member state, in accordance with art 32) and in accordance with Annex I Introduction; or (2) in the circumstances described in art 26(3), must be accompanied by all relevant data available to the applicant: Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 4(4)(a), (b) (as so substituted). An application in respect of a product which is not an immunological product must be in accordance with certain additional requirements: see reg 4(5), Sch 1 (both as so substituted). There are different additional requirements for an application in respect of an immunological product: see reg 4(6), Sch 2 (both as so substituted). In the case of a product that the applicant intends to import from outside the European Economic Area, the application must in addition be in accordance with EC Directive 2001/82 (OJ L311, 28.11.2001, p 1) art 45: Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 4(7) (as so substituted). An applicant is not required, by virtue of EC Directive 2001/82 (OJ L311, 28.11.2001, p 1) art 12(3)(j) to provide the results of toxicological and pharmacological tests and clinical trials if he can demonstrate that he is entitled to the benefit of any of the provisions of art 13.1(a)(i)-(iii): Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 4(8) (as so substituted). Regulation 4(8) (as substituted) only applies where the applicant claims the benefit of EC Directive 2001/82 (OJ L311, 28.11.2001, p 1) art 13.1(a)(iii) if the product authorised within the European Community to which the application refers has been so authorised for a period of not less than ten years before the making of the application: Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 4(9) (as so substituted).

As to the fees payable on applications see the Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750.

4 Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 4(3) (as substituted: see note 1 supra).

5 As to veterinary medicinal products see PARA 34 note 3 ante.

6 Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 5 (substituted by SI 2002/269). The appropriate requirements are:

- 41 (1) EC Directive 2001/82 (OJ L311, 28.11.2001, p 1) arts 6, 21-26, 28, 30, 58(1)-(3), 71, 83.1(e) (second paragraph), 91, 94, and Annex I Title I Pt 4 Ch II point 1 (sixth paragraph) (Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 5(a) (as so substituted));
- 42 (2) in the case of a product already authorised in another member state, EC Directive 2001/82 (OJ L311, 28.11.2001, p 1) arts 6, 7, 21, 22, 71, 94 and Ch 4 (Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 5(b) (as so substituted)).

As to the refusal of authorisations see PARAS 36-37 post.

7 Ibid reg 9. As to considerations of safety see PARA 15 note 10 ante; provision applied by reg 18(2). As to the fees payable on applications for variations see the Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750.

8 le in accordance with EC Directive 2001/82 (OJ L311, 28.11.2001, p 1) arts 62, 78, 83, 84, 85, 94.

9 Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 11 (substituted by SI 2002/269).

10 Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 10(1). The application must be in accordance with EC Directive 2001/82 (OJ L311, 28.11.2001, p 1) arts 26(3), 28, and must be submitted not earlier than five months before the expiry of the existing authorisation: Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 10(2) (reg 10(2), (3) substituted by SI 2002/269). The application must include any information required under EC Directive 2001/82 (OJ L311, 28.11.2001, p 1) arts 12-15, and the relevant parts of Annex I, not previously submitted to the ministers: Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 10(3) (as so substituted). As to the fees payable on applications for renewal, and annual fees, see the Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750 (amended by SI 2004/3081). For the meaning of 'month' see PARA 22 note 15 ante.

11 Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 10(4).

UPDATE

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SI 1994/2986, SI 1994/2987, SI 1994/3142, SI 1997/322, SI 1998/1046, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. As to marketing and other authorisations see now the Veterinary Medicines Regulations 2009, SI 2009/2297; and PARAS 34A-34D.

35 Authorisations

NOTE 3--Head (1). Directive 2001/82 Annex I replaced: EC Commission Directive 2009/9 (OJ L44, 14.2.2009, p 10) art 1, Annex.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(3) MARKETING AUTHORISATIONS/(iv) Veterinary Medicinal Products/A. MARKETING AUTHORISATIONS/36. Refusal of authorisations on grounds relating to safety, quality or efficacy.

36. Refusal of authorisations on grounds relating to safety, quality or efficacy.

If, in circumstances where there will be no right of appeal¹, the ministers² propose³ to refuse to grant a marketing authorisation⁴ on any grounds relating to safety, quality or efficacy⁵, or to suspend or revoke an authorisation⁶ on those grounds⁷, they must consult⁸ the appropriate committee⁹ or, if there is no such committee, the Commission on Human Medicines¹⁰ and must take account of its advice in coming to a decision¹¹.

If the ministers propose to determine the issue in a way which differs from the advice of the Commission or, where there has been no hearing before and no representations have been made or referred to the Commission, the appropriate committee, they must notify the applicant or authorisation holder accordingly, and, before determining the issue, they must afford him an opportunity of appearing before, and being heard by, a person appointed for the purpose by the ministers, or of making representations in writing to the ministers with respect to that proposal¹². Where the applicant or authorisation holder avails himself of the opportunity of appearing before, and being heard by, a person appointed for the purpose, that person must not, except with the consent of the applicant or authorisation holder, be an officer or servant of any of the ministers¹³, the hearing must be in public if the applicant or authorisation holder so requests¹⁴, and if the applicant or authorisation holder so requests the ministers must furnish to him a copy of the report of the person so appointed¹⁵.

1 Ie under EC Parliament and Council Directive 2001/82 (OJ L311, 28.11.2001, p 1) art 36.4.

2 For the meaning of 'the ministers' see PARA 3 note 3 ante; definition applied by the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 18(2).

3 Ie acting in accordance with ibid reg 5(a) (as substituted): see PARA 35 note 6 ante.

4 As to marketing authorisations see PARA 34 ante.

5 Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 12(1)(a) (reg 12(1) substituted by SI 2002/269). As to considerations of safety see PARA 15 note 10 ante; provision applied by the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 18(2).

6 Ie acting in accordance with ibid reg 11 (as substituted): see PARA 35 ante.

7 Ibid reg 12(1)(b) (as substituted: see note 5 supra).

8 Such consultation must take place before ministers act, except that when, in relation to ibid reg 12(1)(b) (as substituted) (see the text to notes 6-7 supra), ministers consider urgent action necessary to protect human or animal health or the environment, it must take place within three months of their acting: reg 12(2). For the meaning of 'month' see PARA 22 note 15 ante.

9 For the meaning of 'the appropriate committee' see PARA 15 note 5 ante; definition applied by ibid reg 18(2).

10 As to the constitution of the Commission see PARA 13 ante.

11 Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 12(1) (as substituted: see note 5 supra). Where the appropriate committee or the Commission has reason to think that:

- 43 (1) it may be unable to advise the ministers to grant an authorisation (reg 12(1) (as so substituted), Sch 3 para 1(a));
- 44 (2) it may be unable to advise the ministers to grant it unless it contains provisions otherwise than in accordance with the application (Sch 3 para 1(b)); or
- 45 (3) it may advise the ministers to suspend or revoke an authorisation (Sch 3 para 1(c)),

the committee or Commission must notify the applicant or authorisation holder accordingly, and, before giving its advice to the ministers, must afford to him an opportunity of appearing before and being heard by it, or of making representations in writing to it with respect to those grounds (Sch 3 para 1).

Whether the applicant or authorisation holder has been heard or has made representations or not, if the appropriate committee or the Commission advise the ministers that the authorisation ought to be refused, suspended or revoked, or ought, if granted, to contain provisions specified in its advice, the ministers must provisionally determine the issue taking account of that advice and notify the applicant or authorisation holder of such determination and of the advice taken into account, and the notification must include a time within which he can appeal against such determination: Sch 3 para 2. If, within the time allowed in the notification of a provisional determination, in a case where the applicant or authorisation holder has not been heard by or made representations to the Commission, he gives notice to the ministers of his desire to be heard with respect to the provisional determination or advice given to them, or makes representations in writing to them with respect to that provisional determination or advice, then:

- 46 (a) if the applicant or authorisation holder has given notice of his desire to be heard, the ministers must arrange for him to have an opportunity of appearing before, and being heard by, the Commission (Sch 3 para 3(a)); or
- 47 (b) if he has made representations in writing, the ministers must refer those representations to the Commission (Sch 3 para 3(b)),

after which the Commission must report to the ministers its findings and advice and the reasons for that advice (Sch 3 para 3).

12 Ibid reg 12(3). Any such notification must state the advice of the Commission or the appropriate committee and the reasons stated by the Commission or the committee for giving that advice, the proposals of the ministers and the reasons for them: reg 12(4).

13 Ibid reg 12(5)(a).

14 Ibid reg 12(5)(b).

15 Ibid reg 12(5)(c).

UPDATE

34-41 Veterinary Medical Products

SI 1994/2986, SI 1994/2987, SI 1994/3142, SI 1997/322, SI 1998/1046, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. As to marketing and other authorisations see now the Veterinary Medicines Regulations 2009, SI 2009/2297; and PARAS 34A-34D.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(3) MARKETING AUTHORISATIONS/(iv) Veterinary Medicinal Products/A. MARKETING AUTHORISATIONS/37. Refusal of authorisations on other grounds.

37. Refusal of authorisations on other grounds.

If, in circumstances where there will be no right of appeal¹, the ministers² propose³ to refuse to grant a marketing authorisation⁴ on any grounds not relating to safety, quality or efficacy⁵, or to suspend or revoke⁶ an authorisation on grounds not relating to safety, quality or efficacy⁷, then before doing so they must serve a notice on the applicant or authorisation holder stating their proposals and the reasons for them and specifying a time within which he may apply to a person appointed by the ministers⁸. If, within the time allowed after the service of a notice, the applicant or authorisation holder gives notice to the ministers of his desire to be heard by the appointed person, or makes representations in writing to the ministers with respect to their proposals, then, before determining the issue, the ministers must afford to him an opportunity of appearing before and being heard by a person appointed for the purpose by them⁹, or must take those representations into account¹⁰.

1 Ie under EC Parliament and Council Directive 2001/82 (OJ L311, 28.11.2001, p 1) art 36.4.

2 For the meaning of 'the ministers' see PARA 3 note 3 ante; definition applied by the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 18(2).

3 Ie acting in accordance with ibid reg 5(a) (as substituted): see PARA 35 note 6 ante.

4 As to marketing authorisations see PARA 34 ante.

5 Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 13(1)(a) (reg 13(1) substituted by SI 2002/269). As to considerations of safety see PARA 15 note 10 ante; provision applied by the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 18(2).

6 Ie acting in accordance with ibid reg 11 (as substituted): see PARA 35 ante.

7 Ibid reg 13(1)(b) (as substituted: see note 5 supra).

8 Ibid reg 13(1) (as substituted: see note 5 supra). This provision does not apply if the ministers are acting in accordance with EC Directive 2001/82 (OJ L311, 28.11.2001, p 1) art 30(e) (first or second paragraphs), or art 83(e) (first or second paragraphs): Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 13(1) (as so substituted).

Any notice or other document required or authorised to be served on any person, or to be given or sent to any person, may be served, given or sent: (1) by delivering it to him; or (2) by sending it by post to him at his usual or last-known residence or place of business in the United Kingdom; or (3) in the case of a body corporate, by delivering it to the secretary or clerk of the body corporate at its registered or principal office or sending it by post to the secretary or clerk of that body corporate at that office: Medicines Act 1968 s 127; applied by the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 18(2). For the meaning of 'United Kingdom' see PARA 7 note 3 ante. As to the registered office of a company see COMPANIES vol 14 (2009) PARA 129. Where an Act authorises or requires any document to be served by post (whether the expression 'serve' or the expression 'give' or 'send' or any other expression is used) then, unless the contrary intention appears, the service is deemed to be effected by properly addressing, pre-paying and posting a letter containing the document and, unless the contrary is proved, to have been effected at the time at which the letter would be delivered in the ordinary course of post: Interpretation Act 1978 s 7.

9 When a person is so appointed the provisions of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 12(5) (see PARA 36 ante) have effect: reg 13(3).

10 Ibid reg 13(2).

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SI 1994/2986, SI 1994/2987, SI 1994/3142, SI 1997/322, SI 1998/1046, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. As to marketing and other authorisations see now the Veterinary Medicines Regulations 2009, SI 2009/2297; and PARAS 34A-34D.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(3) MARKETING AUTHORISATIONS/(iv) Veterinary Medicinal Products/A. MARKETING AUTHORISATIONS/38. Duties on holders of authorisations.

38. Duties on holders of authorisations.

After a marketing authorisation has been issued¹, the holder of that authorisation must comply with the specified requirements², including specified information to be provided on labels and package inserts³. Where a product to which a marketing authorisation relates is imported from outside the European Economic Area, the holder of that marketing authorisation must comply with the specified provision⁴ and must obtain an undertaking from the manufacturer that the manufacturer will comply with certain requirements⁵. Where the holder of a marketing authorisation imports the products to which the authorisation relates from outside the European Economic Area⁶ he must have permanently and continuously at his disposal the services of at least one qualified person⁷, although he may himself undertake the duties of a qualified person if he satisfies the appropriate conditions⁸. Where, after the holder of a marketing authorisation and the person acting as qualified person have been given the opportunity to make written or oral representations, the ministers have served written notice on the holder of the marketing authorisation stating that the person acting as the qualified person does not satisfy the necessary requirements⁹, or that the person has failed to carry out the duties required¹⁰, the holder of the marketing authorisation must not permit that person to act as a qualified person for him unless that notice is withdrawn¹¹.

1 As to marketing authorisations see PARA 34 ante; and as to the issue of marketing authorisations see PARA 35 ante.

2 Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 6(1) (substituted by SI 2002/269). The specified requirements are:

- 48 (1) EC Parliament and Council Directive 2001/82 (OJ L311, 28.11.2001, p 1) arts 12.3.m (second paragraph), 26-28, 58-61, 74, 75, 81.1, 81.2 (second paragraph), 91.2, Annex I introduction (third paragraph), and, if appropriate, Title I Pt 4 Ch II.1 (final paragraph) and Title I Pt 4 Ch III.2.1 (final paragraph) (Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 6(1)(a) (as so substituted));
- 49 (2) any directions given by the ministers in accordance with EC Parliament and Council Directive 2001/82 (OJ L311, 28.11.2001, p 1) art 84 (Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 6(1)(b) (as so substituted));
- 50 (3) the requirement in EC Parliament and Council Directive 2001/82 (OJ L311, 28.11.2001, p 1) art 81 to provide the information specified therein (Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 6(1)(c) (as so substituted));
- 51 (4) EC Parliament and Council Directive 2001/82 (OJ L311, 28.11.2001, p 1) Annex I Title I Pt 2 para C.a (for veterinary medicinal products other than immunological veterinary medicinal products) or Title II Pt 6 para C.a (for immunological medicinal products) (Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 6(1)(d) (as so substituted)).

For the meaning of 'the ministers' see PARA 3 note 3 ante; definition applied by reg 18(2). As to veterinary medicinal products see PARA 34 note 3 ante. It is an offence to contravene these provisions: see PARA 39 post.

3 Ibid reg 6(2). The specified information is that, in addition to the requirements in the provisions referred to in reg 6(1) (as substituted) (see note 2 supra) relating to information to be provided on labels and package inserts, the holder of a marketing authorisation must ensure that labels and package inserts:

- 52 (1) include the words 'store out of reach of children' (reg 6(2)(a));
- 53 (2) include the following initials in a box within which there is no other written material:

3. (a) in the case of a product categorised under the Medicines Act 1968 as a medicinal product on prescription only (that is, a prescription only medicine), the capital letters 'POM' (Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 6(2)(b)(i));
3
 4. (b) in the case of a product categorised under the Medicines Act 1968 as a pharmacy and merchants' list product, the capital letters 'PML' (Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 6(2)(b)(ii));
4
 5. (c) in the case of a product categorised under the Medicines Act 1968 as a medicinal product on a general sale list, the capital letters 'GSL' (Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 6(2)(b)(iii));
5
 6. (d) in the case of an authorised medicated pre-mix, as defined in the Medicated Feedingstuffs Regulations 1998, SI 1998/1046, reg 2(1), other than one which falls within head (e) infra, the capital letters 'MFS' (Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 6(2)(b)(iiiA) (reg 6(2)(b)(iiiA), (iiiB) added by SI 1998/1048));
6
 7. (e) in the case of an authorised medicated pre-mix, as so defined, which falls within the Medicated Feedingstuffs Regulations 1998, SI 1998/1046, regs 18(3), 21(3), 28(4), the capital letters 'MFSX' (Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 6(2)(b)(iiiB) (as so added));
7
 8. (f) in any other case the capital letter 'P' (reg 6(2)(b)(iv));
8
- 54 (3) do not include any reference to the Medicines Act 1968, the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142 (as amended), any committee established under the Medicines Act 1968 s 4 (as amended) (see PARA 15 ante), the Medicines Commission established under s 2 (repealed) (now replaced by the Commission on Human Medicines: see PARA 13 ante), the Committee for Medicinal Products for Veterinary Use or the Committee for Veterinary Medicinal Products (Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 6(2)(b)(c) (amended by SI 2004/3224));
 - 55 (4) do not refer to any other product except in accordance with the marketing authorisation (Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 6(2)(d)); and
 - 56 (5) do not falsely describe the product, or mislead as to its nature, quality, uses or effects (reg 6(2)(e)).

It is an offence to contravene these provisions: see PARA 39 post. For the meanings of 'label' and 'package' see PARA 152 note 4 post; definitions applied by reg 18(2). As to the sale and supply of medicinal products under the Medicines Act 1968 see PARA 133 et seq post. 'The Committee for Medicinal Products for Veterinary Use' has the same meaning as in EC Parliament and Council Regulation 726/2004 (OJ L317, 30.4.2004, p 1) laying down community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Title IV: Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 1(4)(a) (substituted by SI 2004/3224).

4 le EC Directive 2001/82 (OJ L311, 28.11.2001, p 1) art 50(c).

5 Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 7(1) (reg 7 substituted by SI 2002/269). The manufacturer must comply with any conditions attached to the authorisation (Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 7(2) (as so substituted) and comply with the provisions of EC Directive 2001/82 (OJ L311, 28.11.2001, p 1) art 50 paras (a), (b), (d), (e) (Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 7(3) (as so substituted)). In accordance with EC Directive 2001/82 (OJ L311, 28.11.2001, p 1) art 81(1), the manufacturer must give to the ministers on request the data specified in that article: Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 7(4) (as so substituted). The manufacturer must comply with the principles and guidelines of good manufacturing practice as set out in EC Commission Directive 91/412 (OJ L228, 17.8.1991, p 70) arts 4-14 as interpreted in accordance with art 3 (second paragraph) (Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 7(5) (as so substituted)), provided that in order to comply with the provisions of EC Directive 91/412 (OJ L228, 17.8.1991, p 70) art 12 the manufacturer must ensure that the terms of the contract require that the contractor complies with the requirements of art 12.3 and 12.4 (Marketing Authorisations for Veterinary

Medicinal Products Regulations 1994, SI 1994/3142, reg 7(6)(as so substituted)). It is an offence to contravene these provisions: see PARA 39 post.

6 Ibid reg 8(1) (reg 8 substituted by SI 2002/269).

7 Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 8(2) (as substituted: see note 6 supra). The qualified person must satisfy the requirements on qualifications set out in EC Directive 2001/82 (OJ L311, 28.11.2001, p 1) art 53, or be permitted to act as a qualified person by virtue of the provisions of art 54: Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 8(2) (as so substituted). The qualified person must carry out the duties in EC Directive 2001/82 (OJ L311, 28.11.2001, p 1) art 55: Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 8(4) (as so substituted). It is an offence to contravene these provisions: see PARA 39 post.

8 Ibid reg 8(3) (as substituted: see note 6 supra). In order to so act he must satisfy the provisions of EC Directive 2001/82 (OJ L311, 28.11.2001, p 1) art 53 or art 54: Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 8(3) (as so substituted).

9 Ie those of EC Directive 2001/82 (OJ L311, 28.11.2001, p 1) art 53 or art 54. As to the service of notices see PARA 37 note 8 ante.

10 Ie by the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 8 (as substituted).

11 Ibid reg 8(5) (as substituted: see note 6 supra). It is an offence to contravene this provision: see PARA 39 post.

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SI 1994/2986, SI 1994/2987, SI 1994/3142, SI 1997/322, SI 1998/1046, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. As to marketing and other authorisations see now the Veterinary Medicines Regulations 2009, SI 2009/2297; and PARAS 34A-34D.

38 Duties on holders of authorisations

NOTE 2--Heads (1), (4). Directive 2001/82 Annex I replaced: EC Commission Directive 2009/9 (OJ L44, 14.2.2009, p 10) art 1, Annex.

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39. Enforcement and offences.

It is the duty¹ of the Secretary of State² to enforce the provisions relating to marketing authorisations for veterinary medicinal products³. Any person⁴ contravening those provisions⁵ is guilty of an offence⁶. Where the holder of a marketing authorisation is charged with an offence in respect of anything which has been manufactured or assembled⁷ to his order by another person and has been so manufactured or assembled as not to comply with the provisions of that authorisation, it is a defence for him to prove that he had communicated the provisions relating to the authorisation to that other person⁸, and that he did not know, and could not by the exercise of reasonable care have known, that those provisions had not been complied with⁹.

Various provisions of the Medicines Act 1968 relating to enforcement and offences apply to marketing authorisations as they apply to product licences granted under the Act¹⁰.

1 Such duty is deemed to be a duty imposed by the Medicines Act 1968 s 108 (see PARA 168 post), as appropriate: Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 18(7).

2 As to the Secretary of State see PARA 3 note 3 ante.

3 I.e. the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142 (as amended) (see PARAS 34-38 ante): see reg 18(7); the Transfer of Functions (Medicines and Poisons) Order 1999, SI 1999/3142, art 2(3); and the Ministry of Agriculture, Fisheries and Food (Dissolution) Order 2002, SI 2002/794, art 2.

4 For the meaning of 'person' see PARA 21 note 7 ante.

5 I.e. the provisions of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, regs 3, 6-8: see PARAS 34, 38 ante. As to the admissibility of evidence in cases relating to alleged contravention of reg 3 see *Department for the Environment, Food and Rural Affairs v Atkinson* [2002] EWHC 2029 (Admin), [2002] All ER (D) 116 (Oct), DC.

6 See the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 16(1). The penalty on summary conviction is a fine not exceeding the statutory maximum, and on conviction on indictment is a fine or imprisonment for a term not exceeding two years or both: reg 16(1)(a), (b). As to the statutory maximum see PARA 32 note 3 ante.

7 As to the meaning of 'manufacture' see PARA 7 note 2 ante, and for the meaning of 'assemble' see PARA 6 note 8 ante; definitions applied by *ibid* reg 18(2).

8 *Ibid* reg 17(a).

9 *Ibid* reg 17(b).

10 See *ibid* reg 18(2). The provisions of the Medicines Act 1968 referred to in the text are: ss 67, 68 (offences and provision for disqualification) (see PARA 182 post), s 108 (enforcement) (see PARA 168 post), s 111 (rights of entry) (see PARA 169 post), ss 112 (powers to inspect, take samples and seize goods and documents), 113 (application of sampling procedures) (see PARA 170 post), s 114 (supplementary provisions) (see PARA 172 post), s 115 (analysis of samples) (see PARA 171 post), s 119 (protection of officers of enforcement authorities) (see PARA 175 post), s 121 (contravention due to default of another person) (see PARA 179 post), ss 122 (warranty as defence), 123 (offences in relation to warranties) (see PARA 180 post), s 124 (offences by bodies corporate) (see PARA 181 post), ss 125 (prosecutions), 126 (presumptions) (see PARAS 183-184 post): Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 18(2). As to product licences see PARA 44 post.

UPDATE

34-41 Veterinary Medical Products

SI 1994/2986, SI 1994/2987, SI 1994/3142, SI 1997/322, SI 1998/1046, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. As to marketing and other authorisations see now the Veterinary Medicines Regulations 2009, SI 2009/2297; and PARAS 34A-34D.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(3) MARKETING AUTHORISATIONS/(iv) Veterinary Medicinal Products/B. RESTRICTIONS ON THE ADMINISTRATION OF UNAUTHORISED VETERINARY MEDICINAL PRODUCTS/40. Restrictions and exemptions.

B. RESTRICTIONS ON THE ADMINISTRATION OF UNAUTHORISED VETERINARY MEDICINAL PRODUCTS

40. Restrictions and exemptions.

No person¹ may administer² or cause or permit to be administered any veterinary medicinal product³ to an animal unless that product is an authorised veterinary medicinal product⁴. However, this does not prohibit:

- 62 (1) the administration of a veterinary medicinal product to an animal where it is administered for the purpose of:
 - 11
 - 11. (a) a medicinal test on animals in accordance with the Medicines Act 1968⁵, or in connection with that test, where the product is authorised⁶ elsewhere than in the United Kingdom⁷ and is administered for the purpose of comparing the efficacy of the product the subject of the test⁸; or
 - 12. (b) a test on animals in accordance with the provisions of a licence granted under the Animals (Scientific Procedures) Act 1986⁹;
 - 12
 - 63 (2) the administration by a veterinary surgeon or by a person acting under his direction of a ready-made veterinary medicinal product¹⁰ imported and sold or supplied in accordance with specified provisions¹¹;
 - 64 (3) a veterinary surgeon or a person acting under his direction, in the circumstances where no authorised veterinary medicinal product exists for a condition in a particular species and where the veterinary surgeon considers it necessary to avoid causing unacceptable suffering to the animal or animals concerned, administering to a particular animal under his care or a small number of such animals which are kept on the same premises a veterinary medicinal product authorised for use in another animal species or for another condition in the same species¹², or if there is no such product a medicinal product authorised for use in human beings¹³, or if there is no such product authorised for use in human beings a product prepared extemporaneously by any person lawfully authorised in the United Kingdom to do so, in accordance with the terms of a veterinary prescription¹⁴.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 'Administer' includes import for the purposes of administration; and cognate expressions are to be construed accordingly: Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994, SI 1994/2987, reg 2(1), (2) (as substituted: see note 2 supra). For the meaning of 'member state' see the European Communities Act 1972 s 1(2), Sch 1 Pt II; and the Interpretation Act 1978 s 5, Sch 1.

3 'Veterinary medicinal product' has the same meaning as in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) on the approximation of the laws of the member states relating to veterinary medicinal products (amended by EC Council Directive 90/676 (OJ L373, 31.12.1990, p 26)) (see EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 1.2): Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994, SI 1994/2987, reg 2(1), (2) (as substituted: see note 2 supra). For the meaning of 'member state' see the European Communities Act 1972 s 1(2), Sch 1 Pt II; and the Interpretation Act 1978 s 5, Sch 1.

4 Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994, SI 1994/2987, reg 3 (as substituted: see note 2 supra). 'Authorised veterinary medicinal product' means a veterinary medicinal product: (1) which has a marketing authorisation within the meaning of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142 (as amended) (see PARA 34 ante); (2) the administration of which has been authorised by the ministers (see PARA 3 note 3 ante) in accordance with EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 4.1 (second paragraph) or allowed by those ministers in accordance with art 4.1 (third paragraph); (3) which has a product licence under the Medicines Act 1968 (see PARA 44 post); or (4) which is registered under the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322 (as amended) (see PARA 214 post): Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994, SI 1994/2987, reg 2(1) (as so substituted). As to the enforcement of these provisions and offences in relation to them see PARA 41 post.

5 le the Medicines Act 1968 ss 32, 33: see PARAS 127-128 post.

6 le in accordance with EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) (as amended).

7 For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

8 Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994, SI 1994/2987, reg 4(1)(a) (as substituted: see note 2 supra).

9 Ibid reg 4(1)(b) (as substituted: see note 2 supra). As to the Animals (Scientific Procedures) Act 1986 see ANIMALS vol 2 (2008) PARA 875 et seq.

10 'Ready-made veterinary medicinal product' has the same meaning as in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 1.2: Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994, SI 1994/2987, reg 2(2) (as substituted: see note 2 supra).

11 Ibid reg 4(2) (as substituted: see note 2 supra). The specified provisions are the Medicines (Veterinary Medicinal Products) (Veterinary Surgeons from Other EEA States) Regulations 1994, SI 1994/2986 (as amended): see PARA 34 ante.

12 Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994, SI 1994/2987, reg 5(1)(a) (as substituted: see note 2 supra). Specific conditions apply where the carcase or part of the carcase or produce of an animal treated is intended for human consumption: see reg 5(2) (as so substituted). In the circumstances referred to in the text, nothing prohibits a veterinary surgeon or a person acting under his direction from administering to an animal or animals of a minor or exotic species any product such as is mentioned in reg 5(1)(a)-(c) (as substituted) as he thinks fit, so long as no carcase or part of a carcase of, or any produce from, such animal is intended for human consumption: reg 5(3) (as so substituted).

13 Ibid reg 5(1)(b) (as substituted: see note 2 supra). See also note 12 supra. 'Medicinal product authorised for use in human beings' means a medicinal product which has a marketing authorisation within the meaning of the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144 (as amended) (see PARA 20 note 5 ante), which has a product licence under the Medicines Act 1968 for use in human beings, or which has a certificate of registration under the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105 (as amended) (see PARA 205 post): Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994, SI 1994/2987, reg 2(1) (as so substituted).

14 Ibid reg 5(1)(c) (as substituted: see note 2 supra). See also note 12 supra.

UPDATE

34-41 Veterinary Medical Products

SI 1994/2986, SI 1994/2987, SI 1994/3142, SI 1997/322, SI 1998/1046, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. As to marketing and other authorisations see now the Veterinary Medicines Regulations 2009, SI 2009/2297; and PARAS 34A-34D.

40 Restrictions and exemptions

NOTES--Certain persons or indorsements mentioned in this paragraph are specified for the purposes of Regulatory Enforcement and Sanctions Act 2008 s 37, Schs 5, 6

(meaning of 'regulator' for the purposes of imposing civil sanctions), see ADMINISTRATIVE LAW vol 1(1) (2001 Reissue) PARA 196A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(3) MARKETING AUTHORISATIONS/(iv) Veterinary Medicinal Products/B. RESTRICTIONS ON THE ADMINISTRATION OF UNAUTHORISED VETERINARY MEDICINAL PRODUCTS/41. Enforcement and offences.

41. Enforcement and offences.

It is the duty of the Secretary of State¹ to enforce the provisions² relating to the restrictions on the administration of unauthorised veterinary medicinal products³.

If a person⁴ contravenes any of those provisions he is guilty of an offence and liable to a penalty⁵. Where an offence which has been committed by a body corporate is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, any director, manager, secretary or other similar officer of the body corporate or any person who was purporting to act in any such capacity he, as well as the body corporate, is guilty of that offence and liable to be proceeded against and punished accordingly⁶. In any proceedings for an offence, it is a defence for the person charged to prove that he took all reasonable precautions and exercised all due diligence to avoid the commission of such an offence by himself or by a person acting under his direction⁷.

1 See the Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994, SI 1994/2987, reg 6(1)(a), (b); and the Ministry of Agriculture, Fisheries and Food (Dissolution) Order 2002, SI 2002/794, art 2. As to the Secretary of State see PARA 3 note 3 ante.

2 I.e. the provisions of the Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994, SI 1994/2987 (as amended): see PARA 40 ante.

3 Ibid reg 6(1). Such duty is deemed to be a duty imposed by the Medicines Act 1968 s 108 (see PARA 168 post): see the Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994, SI 1994/2987, reg 6(1). The provisions of the Medicines Act 1968 ss 108, 111-114, 119 (see PARAS 168-172, 175 post) apply for these purposes as if the Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994, SI 1994/2987 (as amended) had been made under that Act, and as if an offence contrary to, and proceedings under, the regulations were an offence and proceedings under the Act: Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994, SI 1994/2987, reg 6(2).

4 For the meaning of 'person' see PARA 21 note 7 ante.

5 See the Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994, SI 1994/2987, reg 7. In the case of a contravention in relation to an animal where the carcase or part of the carcase or produce of that animal is intended for, or has been sold or supplied for, human consumption, he is liable on summary conviction to a fine not exceeding the statutory maximum or on conviction on indictment to a fine; and, in any other case, he is liable on summary conviction to a fine not exceeding level 3 on the standard scale: reg 7(a), (b). As to the statutory maximum see PARA 32 note 3 ante. As to the standard scale see PARA 6 note 22 ante.

6 Ibid reg 9(1). When the affairs of a body corporate are managed by its members, reg 9(1) applies in relation to the acts and defaults of a member in connection with his functions of management as if he were a director of the body corporate: reg 9(2). As to bodies corporate see COMPANIES; CORPORATIONS.

UPDATE

UPDATE

34-41 Veterinary Medical Products

SI 1994/2986, SI 1994/2987, SI 1994/3142, SI 1997/322, SI 1998/1046, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to

veterinary medicinal products. As to marketing and other authorisations see now the Veterinary Medicines Regulations 2009, SI 2009/2297; and PARAS 34A-34D.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(4) LICENCES AND LICENSING/(i) In general/42. Introduction.

(4) LICENCES AND LICENSING

(i) In general

42. Introduction.

The sale, supply, importation or exportation of medicinal products is prohibited except in accordance with a product licence¹. However, this prohibition does not apply to medicinal products or veterinary medicinal products for which a marketing authorisation is needed², nor to investigational medicinal products subject to the clinical trials regime³. The manufacture and assembly of medicinal products is prohibited except in accordance with a manufacturer's licence⁴ and a medicinal product may only be distributed by way of wholesale dealing in accordance with a wholesale dealer's licence⁵. There are various exemptions from these restrictions⁶.

Applications for licences must be made to the licensing authority⁷, which also has powers to suspend, vary or revoke licences on certain grounds⁸. Decisions of the licensing authority in respect of licences may only be challenged on specified grounds⁹.

1 See the Medicines Act 1968 s 7 (as amended); and PARA 44 post.

2 See the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 9(2) (see PARA 20 ante); and the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 18(1) (see PARA 34 ante).

3 See the Medicines Act 1968 s 7(3A) (as added); and PARA 44 post.

4 See *ibid* s 8 (as amended); and PARA 46 post.

5 See *ibid* s 8 (as amended); and PARA 47 post.

6 See *ibid* ss 9-15 (as amended); and PARAS 49-55 post.

7 See *ibid* ss 18-22 (as amended); and PARAS 43, 56-68 post.

8 See *ibid* ss 28-30 (s 28 as amended); and PARAS 69-78 post.

9 See *ibid* s 107; and PARA 79 post.

UPDATE

42 Introduction

NOTE 2--SI 1994/3142 revoked: SI 2005/2745.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(4) LICENCES AND LICENSING/(ii) The Licensing Authority/43. The licensing authority.

(ii) The Licensing Authority

43. The licensing authority.

The authority responsible for the grant¹, renewal², variation, suspension and revocation³ of licences⁴ and certificates⁵ is a body of ministers consisting of the health ministers⁶ and the agriculture ministers⁷. Any function conferred on the licensing authority by or under the Medicines Act 1968 may be performed by any one of those ministers acting alone or by any two or more of them acting jointly⁸.

1 As to the grant of licences see PARA 61 post.

2 As to the renewal of licences see PARA 68 post.

3 As to the variation, suspension and revocation of licences see PARA 70 post.

4 I.e. licences granted under the Medicines Act 1968 Pt II (ss 6-50) (as amended): see PARA 44 et seq post.

5 As to certificates see PARA 130 et seq post.

6 For the meaning of 'the health ministers' see PARA 3 note 4 ante.

7 Medicines Act 1968 s 6(1). For the meaning of 'the agriculture ministers' see PARA 3 note 5 ante. The duty of the licensing authority is to safeguard the health of the nation and it must act fairly and equally between applicants; it cannot fulfil those obligations without having recourse to all the information available to it, confidential or otherwise: *Re Smith Kline & French Laboratories Ltd* [1990] 1 AC 64, sub nom *Smith Kline & French Laboratories Ltd v Licensing Authority* [1989] 1 All ER 578, HL.

8 Medicines Act 1968 s 6(2). Accordingly, 'the licensing authority' means any one or more of those ministers and, in the case of anything falling to be done by the licensing authority, means any one or more of those ministers acting as mentioned in s 6(2): ss 6(3), 132(1).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(4) LICENCES AND LICENSING/(iii) Prohibitions/44. Product licence.

(iii) Prohibitions

44. Product licence.

Subject to certain exemptions¹, no person² in the course of a business³ carried on by him may⁴, except in accordance with a product licence⁵, sell, supply or export⁶ any medicinal product⁷, procure the sale, supply or exportation of any such product⁸, or procure the manufacture⁹ or assembly¹⁰ of any such product for sale, supply or exportation¹¹.

The circumstances in which a product licence is required, in relation to an imported¹² medicinal product, are those in which the person selling, supplying or exporting the product in question or procuring its sale, supply or exportation or its manufacture or assembly for sale, supply or exportation has himself imported the product or procured its importation¹³. The circumstances in which a product licence is required, in relation to any medicinal product which has not been imported, are those in which the person selling, supplying or exporting the product in question or procuring its sale, supply or exportation or its manufacture or assembly for sale, supply or exportation is responsible for the composition¹⁴ of the product¹⁵ or, in the case of a proprietary medicinal product¹⁶, a ready-made veterinary drug¹⁷ or an industrially produced medicinal product other than a veterinary drug, is responsible for the placing of that product on the market in the United Kingdom¹⁸. A person is taken to be responsible for the composition of a medicinal product if, but only if, in the course of a business carried on by him he procures the manufacture of the product to his order by another person, where the order specifies or incorporates by reference to some other document particulars of the composition of the product ordered, whether those particulars amount to a complete specification or not¹⁹, or he manufactures the product otherwise than in pursuance of such an order²⁰.

Subject to certain exemptions²¹, no person may import any medicinal product except in accordance with a product licence²².

Except in certain circumstances, it is an offence to administer to any animal any veterinary medicinal product unless a product licence has been granted in respect of it²³.

1 le the exemptions conferred by or under the Medicines Act 1968 Pt II (ss 6-50) (as amended) (see PARA 49 et seq post); s 7(1)(a). Section 7 also has effect subject to the provisions of Pt II (as amended) relating to medicinal tests on animals (see ss 31-39; and PARA 126 et seq post) (s 7(1)(b)), and to the provisions of s 48 (see PARA 12 ante) (s 7(1)(c)). Section 7 does not apply in relation to relevant medicinal products under the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144 (as amended) (see PARA 20 et seq ante) (reg 9(2)); to the placing on the market, or import for those purposes, of a veterinary medicinal product to which the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142 (as amended) apply (see PARA 34 ante) (reg 18(1) (amended by SI 2000/776)); nor in relation to traditional herbal medicinal products (see PARA 230 post): Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, SI 2005/2750, reg 10(1).

2 For the meaning of 'person' see PARA 21 note 7 ante.

3 As to the meaning of 'business' see PARA 7 note 11 ante.

4 As to the circumstances in which this provision applies see the text and notes 12-20 infra.

5 'Product licence' means a licence granted for the purposes of the Medicines Act 1968 s 7: ss 7(2), 132(1).

6 For the meaning of 'export' see PARA 7 note 4 ante. As to the postponement of export prohibitions see PARA 12 ante.

7 Medicines Act 1968 s 7(2)(a). For the meaning of 'medicinal product' see PARA 7 ante. The restrictions imposed by s 7(2) and (3) (see the text to notes 21-22 *infra*) do not apply where the medicinal product concerned is a homoeopathic medicinal product to which the EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) applies and which fulfils the conditions laid down in article 14(1) of that Directive: Medicines Act 1968 s 7(3B) (added by the Medicines (Homoeopathic Medicinal Products for Human Use) Amendment Regulations 2005, SI 2005/2753, reg 21, Schedule para 1(3)). 'Homoeopathic medicinal product' means any medicinal product (which may contain a number of principles) prepared from substances called homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by any pharmacopoeia used officially in a member state: Medicines Act 1968 s 7(7) (s 7(7) added by the Medicines (Medicines Act 1968 Amendment) Regulations 1977, SI 1977/1050, reg 2, and substituted by the Medicines (Medicines Act 1968 Amendment) Regulations 1983, SI 1983/1724, reg 2(3); definition added by the Medicines Act 1968 (Amendment) (No 2) Regulations 1994, SI 1994/276, reg 3(2), and amended by the Medicines (Homoeopathic Medicinal Products for Human Use) Amendment Regulations 2005, SI 2005/2753, Schedule para 1(4)). For the meaning of 'substance' see PARA 7 note 1 ante. As to homoeopathic medicinal products see PARA 205 *et seq post*. As to pharmacopoeia see PARA 149 *post*.

The restrictions imposed by the Medicines Act 1968 s 7(2), (3) (see the text to notes 21-22 *infra*) do not apply where the medicinal product concerned is an investigational medicinal product within the meaning of the clinical trials regulations (see PARA 82 note 1 *post*): s 7(3A) (added by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 54, Sch 10 Pt 1 para 4). For the meaning of 'the clinical trials regulations' see PARA 9 note 10 ante.

Contravention of the Medicines Act 1968 s 7 (as amended) is an offence under s 45: see s 45(1); and PARA 176 *post*. The provisions of s 7 (as amended) do not apply to anything done before 1 September 1971: s 16(1). For the extension of these provisions in certain circumstances see s 43; and PARA 45 *post*. As to the licensing authority see PARA 43 ante. As to applications for licences see PARA 56 *et seq post*; and as to revocation of licences see PARA 70 *post*.

8 *Ibid* s 7(2)(b). See also note 7 *supra*.

9 As to the meaning of 'manufacture' see PARA 7 note 2 ante.

10 For the meaning of 'assembly' see PARA 6 note 8 ante.

11 Medicines Act 1968 s 7(2)(c). See also note 7 *supra*.

12 For the meaning of 'import' see PARA 7 note 3 ante.

13 Medicines Act 1968 s 7(4).

14 'Composition', in relation to a medicinal product, means the ingredients of which it consists and the proportions, and the degrees of strength, quality and purity, in which they are contained in it: *ibid* s 132(1). As to the meaning of 'ingredient' see PARA 7 note 7 ante.

15 *Ibid* s 7(5)(a) (s 7(5)(a) substituted by the Medicines (Medicines Act 1968 Amendment) Regulations 1977, SI 1977/1050, reg 2(2)).

16 'Proprietary medicinal product' means a ready-prepared medicinal product placed on the market in the United Kingdom under a special name and in a special pack: Medicines Act 1968 s 7(7) (s 7(7) as added and substituted (see note 7 *supra*); definition substituted by the Medicines Act 1968 (Amendment) Regulations 1992, SI 1992/604, reg 2). For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

17 'Ready-made veterinary drug' means a ready-prepared veterinary drug placed on the market in the United Kingdom in a pharmaceutical form in which it may be used without further processing, not being a drug placed on the market under a special name and in a special pack: Medicines Act 1968 s 7(7) (s 7(7) as added and substituted (see note 7 *supra*); definition amended by the Medicines Act 1968 (Amendment) Regulations 1992, SI 1992/604, reg 2). For the meaning of 'veterinary drug' see PARA 3 note 7 ante.

18 Medicines Act 1968 s 7(5)(b) (substituted by the Medicines (Medicines Act 1968 Amendment) Regulations 1977, SI 1977/1050, reg 2(2); and amended by the Medicines Act 1968 (Amendment) Regulations 1992, SI 1992/604, reg 2). Medicinal products of any description are taken to be effectively on the market in the United Kingdom at a particular time if, but only if, during the whole of the month ending with that time adequate stocks of medicinal products of that description were available, or could within a reasonable time be made available, for sale or supply to such persons in the United Kingdom as were likely to require them: Medicines Act 1968 s 132(5). For the meaning of 'month' see PARA 22 note 15 ante.

Section 7(5)(b) (as substituted and amended) does not apply where the product which the person is responsible for placing on the market in the United Kingdom: (1) is not a veterinary drug, and is a radiopharmaceutical in which the radionuclide is in the form of a sealed source (s 7(6A)(b) (added by the Medicines Act 1968 (Amendment) Regulations 1992, SI 1992/604, reg 2; and amended by the Medicines Act 1968 (Amendment) (No 2) Regulations 1994, SI 1994/276, reg 3(1), (3); and the Blood Quality and Safety Regulations 2005, SI 2005/50, reg 25)); or (2) is a veterinary drug, and is: (a) a vaccine, toxin or serum; (b) a product based on radioactive isotopes; (c) a product specially prepared for administration by a veterinary surgeon or practitioner to a particular animal or herd under his care; (d) a homoeopathic medicinal product; or (e) an additive for animal feeding stuffs to which EC Council Directive 70/524 (OJ L270, 14.12.1970, p 1) applies (Medicines Act 1968 s 7(6B) (added by the Medicines Act 1968 (Amendment) Regulations 1992, SI 1992/604, reg 2)). 'Radiopharmaceutical' means a medicinal product which, when ready for use, contains one or more radionuclides included for a medicinal purpose: Medicines Act 1968 s 7(7) (as added and substituted: see note 7 supra). For the meaning of 'a medicinal purpose' see PARA 8 ante. As to the meaning of 'administer' see PARA 7 note 2 ante; and for the meanings of 'veterinary surgeon' and 'veterinary practitioner' see PARA 7 note 10 ante. As to the meaning of 'animal' see PARA 3 note 7 ante; and as to the meaning of 'herd' see PARA 50 note 13 post.

19 Ibid s 7(6)(a).

20 Ibid s 7(6)(b).

21 See note 1 supra.

22 Medicines Act 1968 s 7(3). See also note 7 supra.

23 See the Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994, SI 1994/2987, reg 3 (as substituted); and PARA 40 ante.

UPDATE

44 Product licence

NOTE 1--SI 1994/3142 revoked: SI 2005/2745.

NOTE 23--SI 1994/2987 revoked: SI 2005/2745.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(4) LICENCES AND LICENSING/(iii) Prohibitions/45. Extension of product licence provisions to substances other than medicinal products.

45. Extension of product licence provisions to substances other than medicinal products.

Where in the course of a business¹ carried on by him a person² sells, supplies or exports³ a substance⁴ or article for use wholly or mainly in either or both of the ways in which medicinal products⁵ may be used⁶, and the substance or article, not having been manufactured⁷ or imported⁸ for such use⁹, or previously sold or supplied for such use¹⁰, does not constitute a medicinal product before that person so sells, supplies or exports it, then, subject to certain exceptions¹¹, the product licence provisions¹² have effect in relation to the sale, supply or exportation of the substance or article as if he were selling, supplying or exporting it in circumstances to which those provisions apply¹³.

Where, in the same circumstances, a person proposes to sell, supply or export a substance or article, he may, if he so desires, apply for and be granted a product licence¹⁴.

1 As to the meaning of 'business' see PARA 7 note 11 ante.

2 For the meaning of 'person' see PARA 21 note 7 ante.

3 For the meaning of 'export' see PARA 7 note 4 ante.

4 For the meaning of 'substance' see PARA 7 note 1 ante.

5 For the meaning of 'medicinal product' see PARA 7 ante.

6 I.e. by being administered to one or more human beings or animals for a medicinal purpose or, in certain circumstances, as an ingredient in the preparation of a substance or article which is to be administered to one or more human beings or animals for a medicinal purpose: see the Medicines Act 1968 s 130(1); and PARA 7 ante. As to the meaning of 'administer' see PARA 7 note 2 ante. As to the meaning of 'animal' see PARA 3 note 7 ante. For the meaning of 'a medicinal purpose' see PARA 8 ante. As to the meaning of 'ingredient' see PARA 7 note 7 ante.

7 As to the meaning of 'manufacture' see PARA 7 note 2 ante.

8 For the meaning of 'import' see PARA 7 note 3 ante.

9 Medicines Act 1968 s 43(1)(a).

10 Ibid s 43(1)(b).

11 Ibid s 43(1) does not apply to a transaction by which a person, in the course of a business carried on by him, sells a substance or article by retail or supplies it in circumstances corresponding to retail sale unless in the course of that business the substance or article has been assembled for the purpose of being sold or supplied by him: s 43(2). This reference to assembling a substance or article is a reference to doing, in the course of that business, anything which, in accordance with the definition of 'assemble' (see PARA 6 note 8 ante) would constitute assembling if it had been a medicinal product when sold or supplied to him: s 43(5). As to references to retail sale and selling by retail see PARA 7 note 12 ante.

12 I.e. ibid s 7(2): see PARA 44 ante.

13 Ibid s 43(1). References in Pt II (ss 6-50) (as amended) to the provisions of, or the restrictions imposed by, s 7 (as amended) include references to s 7(2) as extended by s 43(1), (2): s 43(3). See also PARA 12 ante.

14 See ibid s 43(4). Subject to the provisions of ss 19-22A (as amended) (see PARA 58 et seq post), the licensing authority may grant him a product licence in respect of the substance or article as if he were proposing to sell, supply or export it in circumstances to which s 7(2) (see PARA 44 ante) applies: s 43(4)

(amended by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 8, Sch 1 para 8). For the meaning of 'product licence' see PARA 44 note 5 ante. For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

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46. Manufacturer's licence.

Subject to certain exemptions¹, no person², in the course of a business³ carried on by him, may manufacture⁴ or assemble⁵ any medicinal product⁶ except in accordance with a manufacturer's licence⁷.

These restrictions do not, however, apply to the assembly⁸ of any medicinal product where: (1) the medicinal product is for human use and may be lawfully sold by retail⁹ or supplied in circumstances corresponding to retail sale otherwise than by or under the supervision of a pharmacist¹⁰, except where the product may be so sold or supplied by virtue only of the transitional provisions¹¹ relating to certain conditions for products not on a general sale list¹²; (2) the medicinal product is to be sold or supplied by a person who either is a member of a registering body¹³ or customarily administers medicinal products to human beings in the course of a business in the field of osteopathy, chiropody, naturopathy or other similar field¹⁴, and in circumstances where the person selling or supplying it sells or supplies it for administration to a particular person after being requested by or on behalf of that person and in that person's presence to use his own judgment as to the treatment required¹⁵; and (3) a notification in writing¹⁶ has been received by the licensing authority¹⁷ from the person seeking exemption or from a registering body of which he is a member, containing his name and the address at which he proposes to carry out the assembly of any medicinal product in relation to which heads (1) and (2) above are satisfied¹⁸.

Any exemption under these provisions has effect from the date of a direction in writing to that effect from the licensing authority to the person seeking exemption or a registering body of which he is a member¹⁹, and any such exemption applying to a person who is not a member of a registering body continues in force for a period of five years from the date on which it has effect²⁰. The licensing authority may direct that any exemption ceases to have effect, either wholly or to such extent as it considers appropriate, by giving notice²¹ specifying the date from which and the extent to which the exemption is to cease to have effect, in any of the following circumstances: (a) where it appears to the authority at any time that on grounds of safety an exemption should cease to apply to a particular person either wholly or in respect of certain medicinal products²²; (b) where any person who is not a member of a registering body has been requested in writing by the authority to furnish written particulars of any medicinal products being assembled by him to which an exemption applies and has failed to comply within 21 days of the request or such further time as the authority allows²³; or (c) where any person who is not such a member has failed to notify the authority in writing within 21 days of any change in the address at which he is assembling any medicinal product to which an exemption applies²⁴.

Certain substances²⁵ and fluids for use with contact lenses or blanks are also exempted from the restrictions on assembly where certain conditions are met and the assembly is by a doctor, pharmacist or optician²⁶.

1 The licence provisions of the Medicines Act 1968 s 8 (as amended) are subject to the exemptions referred to in s 7(1)(a)-(c) (see PARA 44 note 1 ante): s 8(1). Otherwise s 8 (as amended) has effect without prejudice to the operation of s 7 (as amended): s 8(1). There are exemptions from s 8(2) under s 35(2): see PARA 49 post.

2 For the meaning of 'person' see PARA 21 note 7 ante.

3 As to the meaning of 'business' see PARA 7 note 11 ante.

4 As to the meaning of 'manufacture' see PARA 7 note 2 ante.

5 For the meaning of 'assemble' see PARA 6 note 8 ante.

6 For the meaning of 'medicinal product' see PARA 7 ante.

7 Medicines Act 1968 s 8(2). 'Manufacturer's licence' means a licence granted for the purposes of s 8(2): ss 8(2), 132(1). As to the effect of a manufacturer's licence see PARA 66 post. In the case of a medicinal product that is an investigational medicinal product, the restrictions imposed by s 8(2) only apply if the product has a product licence or marketing authorisation, and to the extent that the manufacture or assembly of the product is in accordance with the terms and conditions of that licence or authorisation: s 8(2A) (s 8(2A), (2B) added by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 54, Sch 10 Pt 1 para 4(1), (2)). 'Investigational medicinal product' has the meaning given by the clinical trials regulations (see PARA 82 note 1 post); and 'marketing authorisation' means a marketing authorisation issued by a competent authority in accordance with EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) (see PARA 20 et seq ante), or a marketing authorisation granted by the European Commission under EC Council Regulation 2309/93 (OJ L214, 24.8.1993, p 1) (as amended) (see PARA 19 ante): Medicines Act 1968 s 8(2B) (as so added). For the meaning of 'product licence' see PARA 44 note 5 ante. For the meaning of 'the clinical trials regulations' see PARA 9 note 10 ante.

Contravention of s 8 (as amended) is an offence under s 45 (see PARA 176 post): s 45(1). The provisions of s 8 (as amended) do not apply to anything done before 1 September 1971: s 16(1). As to applications for licences see PARA 56 et seq post. As to the power to provide for exemptions see s 15; and PARA 49 post.

8 'Assemble', in relation to the exemptions under the Medicines (Exemption from Licences) (Assembly) Order 1979, SI 1979/1114, means to label the container in which a medicinal product is already enclosed and in which it is to be sold or supplied before the product is sold or supplied in it; and 'assembly' has a corresponding meaning: art 1(1). For the meanings of 'label' and 'container' see PARA 152 note 4 post.

9 As to references to retail sale and selling by retail see PARA 7 note 12 ante.

10 'Pharmacist', in relation to Great Britain, means a person registered in the register of pharmaceutical chemists established in pursuance of the Pharmacy Act 1852 and maintained in pursuance of the Pharmacy Act 1954 s 2(1): Medicines Act 1968 s 132(1). As to the register of pharmaceutical chemists see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 888. For the meaning of 'Great Britain' see PARA 7 note 3 ante.

11 See the Medicines (Pharmacy and General Sale--Exemption) Order 1980, SI 1980/1924 (amended by SI 1982/27; SI 1989/1852; SI 1994/2409; SI 1994/3142; SI 1994/3144; SI 1997/1350; SI 1998/107; SI 1998/2368; SI 2000/1919; SI 2002/880; SI 2002/2469; SI 2003/697; SI 2003/1590; SI 2004/1; SI 2004/696; SI 2004/1190; SI 2004/1771; SI 2005/766; SI 2005/848; SI 2005/1507; SI 2005/2750; SI 2005/2759).

12 Medicines (Exemption from Licences) (Assembly) Order 1979, SI 1979/1114, art 2(1), (2)(a). As to references to medicinal products on a general sale list see PARA 133 post.

13 'Registering body' means any professional body whose members customarily administer medicinal products to human beings in the course of their profession and which is required by law to maintain a register of its members: ibid art 1(2). As to the meaning of 'administer' see PARA 7 note 2 ante. As to the regulation of medical professions see MEDICAL PROFESSIONS.

14 Ibid art 2(1), (2)(b)(i). As to the regulation of osteopaths see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 499 et seq; and as to the regulation of chiropodists and other health care professions see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 308 et seq.

15 Ibid art 2(1), (2)(b)(ii).

16 For the meanings of 'writing' and 'written' see PARA 21 note 4 ante.

17 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

18 Medicines (Exemption from Licences) (Assembly) Order 1979, SI 1979/1114, art 2(1), (2)(c).

19 Ibid art 3(1).

20 Ibid art 3(2). If before the end of that period the authority receives from that person a further notification in the form described in art 2(2)(c) (see the text to notes 16-18 supra), the exemption continues in force for a further five years, and the authority must notify him accordingly: art 3(2).

21 Written notice must be given to the person to whom exemption relates, except that, where *ibid* art 4(2) (a) (see the text to note 22 *infra*) applies and that person is a member of a registering body, notice may be given instead to that body: art 4(3).

22 *Ibid* art 4(2)(a).

23 *Ibid* art 4(2)(b).

24 *Ibid* art 4(2)(c).

25 'Contact lens substance' means any substance for use in cleaning, disinfecting, irrigating, lubricating, wetting or storing any contact lens or blank from which the contact lens is to be prepared, or any fluid in which such lens or blank is soaked or rinsed, or any fluid used as a barrier between such lens or blank and the human eyeball, or any other substance used in connection with the use of such lens or blank: Medicines (Contact Lens Fluids and Other Substances) (Exemption from Licences) Order 1979, SI 1979/1585, art 1(2). In the definition of 'contact lens substance', the expression 'contact lens' refers only to a contact lens which consists of a thin curved shell of glass, plastic or other hard or soft material intended for use by being applied to the human eyeball: art 1(2A) (added by SI 1979/1745).

26 See the Medicines (Contact Lens Fluids and Other Substances) (Exemption from Licences) Order 1979, SI 1979/1585, art 2(1). The restrictions on assembly imposed by the Medicines Act 1968 s 8(2) do not apply to the assembly of a contact lens substance by a doctor, pharmacist or optician where the assembly consists only of labelling the container in which the substance is sold or supplied, before it is sold or supplied, and the conditions as to labelling and as to notice to the licensing authority are satisfied: see Medicines (Contact Lens Fluids and Other Substances) (Exemption from Licences) Order 1979, SI 1979/1585, art 2(1), (2). 'Doctor' means a registered medical practitioner: art 1(2) (definition added by SI 2002/3135). For the meaning of 'registered medical practitioner' see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 4. 'Optician' means a person whose name is entered in the register of optometrists maintained under the Opticians Act 1989 s 7(a): Medicines (Contact Lens Fluids and Other Substances) (Exemption from Licences) Order 1979, SI 1979/1585, art 1(2) (definition substituted by SI 2005/848). As to the register of optometrists see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 838.

An exemption has effect from the date of the giving of a notice and continues unless and until terminated by the authority: Medicines (Contact Lens Fluids and Other Substances) (Exemption from Licences) Order 1979, SI 1979/1585, art 3(1). The authority may terminate an exemption, either wholly or so far as it relates to one or more descriptions or classes of contact lens substances, by giving notice in writing to the doctor, pharmacist or optician concerned where it appears to it at any time on grounds of safety that the exemption should cease to have effect, or that doctor, pharmacist or optician has failed to comply with a request from the authority for information as to his work under the exemption: see art 3(2). The date from which an exemption terminated by such a notice ceases to have effect is the date on which the notice is given or such later date as may be specified in it: art 3(3).

UPDATE

46 Manufacturer's licence

TEXT AND NOTES--The Ministers (see PARA 3 NOTE 3) may prescribe requirements (either generally or in relation to a prescribed class of medicinal product or activity) with which the holder of a manufacturer's licence must comply, and which are to have effect as if they were provisions of the licence: 1968 Act s 8(2D) (added by SI 2005/2789).

NOTE 7--Definition of 'marketing authorisation' amended: SI 2008/3097. The prohibition in the 1968 Act s 8(2) also does not apply to a person who, in connection with the importation of a medicinal product from a third country provides facilities solely for transporting the product, or, in the course of a business carried on by him as an import agent, imports the medicinal product solely to the order of another person who holds a manufacturer's licence authorising the importation of the product: s 8(2C) (added by SI 2005/2789).

NOTE 11--SI 1980/1924 further amended: see PARA 137 NOTE 20.

NOTE 26--Definition of 'optician' in SI 1979/1585 art 1(2) further substituted: SI 2007/3101.

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47. Wholesale dealer's licence.

Subject to certain exemptions¹, no person², in the course of a business³ carried on by him, may sell, or offer for sale, any medicinal product⁴ by way of wholesale dealing⁵, or distribute, otherwise than by way of sale, any proprietary medicinal product⁶, ready-made veterinary drug⁷ or industrially produced medicinal product other than a veterinary drug⁸, which has been imported⁹, but was not consigned from a member state¹⁰ of the European Union¹¹, except in accordance with a wholesale dealer's licence¹². Without prejudice to this provision, no person may, in the course of a business carried on by him, distribute by way of wholesale dealing¹³ a product to which the Directive on the Community code relating to medicinal products for human use applies except in accordance with a wholesale dealer's licence¹⁴. Distribution of such a product by way of wholesale dealing must not be taken to be in accordance with a wholesale dealer's licence unless, in particular, it occurs in the course of a business which is carried on at a place or places specified in the licence¹⁵.

1 The licence provisions of the Medicines Act 1968 s 8 (as amended) are subject to the exemptions referred to in s 7(1)(a)-(c) (see PARA 44 note 1 ante): s 8(1). Otherwise s 8 (as amended) has effect without prejudice to the operation of s 7 (as amended): s 8(1). The restrictions imposed by s 8(3) (as substituted and amended) and s 8(3A) (as added and amended) (see the text to note 14 infra) do not apply to anything done in relation to a product to which European Parliament and Council Directive EC 2001/83 (OJ L311, 28.11.2001, p 67) on the Community code relating to medicinal products for human use (as amended) applies by the holder of a manufacturer's licence in respect of it: Medicines Act 1968 s 8(3C) (s 8(3A)-(3C) added by the Medicines Act 1968 (Amendment) Regulations 1993, SI 1993/834, reg 2(4), (5); Medicines Act 1968 s 8(3A), (3C) amended by the Medicines (Codification Amendments Etc) Regulations 2002, SI 2002/236, reg 2(a)(i)). For the meaning of 'manufacturer's licence' see PARA 46 note 7 ante. The restrictions imposed by the Medicines Act 1968 s 8(3) (as substituted and amended) and s 8(3A) (as added and amended) do not apply where the product concerned is an investigational medicinal product (see PARA 82 note 1 post) within the meaning given by the clinical trials regulations: s 8(3D) (added by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 54, Sch 10 Pt 1 para 4(1), (5)). For the meaning of 'the clinical trials regulations' see PARA 9 note 10 ante. Additional exemptions are set out in the Medicines (Exemption from Licences) (Wholesale Dealing) Order 1990, SI 1990/566 (amended by SI 1994/3142; SI 1994/3144).

2 For the meaning of 'person' see PARA 21 note 7 ante.

3 As to the meaning of 'business' see PARA 7 note 11 ante.

4 For the meaning of 'medicinal product' see PARA 7 ante.

5 Medicines Act 1968 s 8(3)(a) (s 8(3) substituted by the Medicines (Medicines Act 1968 Amendment) Regulations 1977, SI 1977/1050, reg 3). Any reference to selling anything by way of wholesale dealing is a reference to selling it to a person who buys it for one or more specified purposes, but does not include any such sale by the person who manufactured it (see PARA 7 note 2 ante): Medicines Act 1968 s 131(1). The specified purposes, in relation to a person to whom anything is sold, are purposes of: (1) selling or supplying it; or (2) administering it (see PARA 7 note 2 ante) or causing it to be administered to one or more human beings, in the course (in either case) of a business carried on by that person: s 131(2). For the purposes of s 131, the provision of services by or on behalf of the Secretary of State under the National Health Service Act 1977 (see HEALTH SERVICES vol 54 (2008) PARA 10 et seq) is to be treated as the carrying on of a business by him: Medicines Act 1968 s 131(5) (amended by the National Health Service Act 1977 s 129, Sch 15 para 49).

6 For the meaning of 'proprietary medicinal product' see PARA 44 note 16 ante; definition applied by the Medicines Act 1968 s 8(6) (added by the Medicines Act 1968 (Amendment) Regulations 1992, SI 1992/604, reg 3).

7 For the meaning of 'ready-made veterinary drug' see PARA 44 note 17 ante; definition applied by the Medicines Act 1968 s 8(6) (as added: see note 6 supra).

8 For the meaning of 'veterinary drug' see PARA 3 note 7 ante.

9 For the meaning of 'import' see PARA 7 note 3 ante.

10 For the meaning of 'member state' see the European Communities Act 1972 s 1(2), Sch 1 Pt II; and the Interpretation Act 1978 s 5, Sch 1.

11 Medicines Act 1968 s 8(3)(b) (as substituted (see note 5 supra); and amended by the Medicines Act 1968 (Amendment) Regulations 1992, SI 1992/604, reg 3). The restriction in the Medicines Act 1968 s 8(3)(b) (as substituted and amended) does not apply in the same circumstances as those in which s 7(5)(b) (as substituted and amended) (see PARA 44 note 18 ante) does not apply: see s 8(4), (5) (s 8(4) substituted, and s 8(5) added, by the Medicines Act 1968 (Amendment) Regulations 1992, SI 1992/604, reg 3; and the Medicines Act 1968 s 8(4) amended by the Medicines Act 1968 (Amendment) (No 2) Regulations 1994, SI 1994/276, reg 4(2); and the Blood Quality and Safety Regulations 2005, SI 2005/50, reg 25).

12 Medicines Act 1968 s 8(3) (as substituted (see note 5 supra) and amended (see note 11 supra); and further amended by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 54, Sch 10 Pt 1 para 4(1), (4)). Any reference to a wholesale dealer's licence is a reference to a licence granted for the purposes of s 8(3) (as substituted and amended) or s 8(3A) (as added): s 8(8) (added by the Medicines Act 1968 (Amendment) Regulations 1993, SI 1993/834, reg 2(1), (5)); Medicines Act 1968 s 132(1). Contravention of s 8(3) (as substituted and amended) is an offence under s 45 (see PARA 176 post): s 45(1). As to applications for licences see PARA 56 et seq post; and as to revocations see PARA 70 post. The provisions of the Medicines Act 1968 s 8 (as amended) do not apply to anything done before 1 September 1971: s 16(1).

13 Any reference to distribution of a product by way of wholesale dealing is a reference to selling or supplying it, or procuring, holding or exporting it for the purposes of sale or supply, to a person who receives it for the purposes of selling or supplying it, or administering it or causing it to be administered to one or more human beings, in the course of a business carried on by that person: *ibid* s 8(7) (added by the Medicines Act 1968 (Amendment) Regulations 1993, SI 1993/834, reg 2(1), (5)). For the meaning of 'export' see PARA 7 note 4 ante.

14 Medicines Act 1968 s 8(3A) (as added and amended (see note 1 supra); and further amended by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, Sch 10 Pt 1 para 4(1), (4)). See also note 1 supra.

15 Medicines Act 1968 s 8(3B) (as added: see note 1 supra).

UPDATE

47 Wholesale dealer's licence

TEXT AND NOTES--The Ministers (see PARA 3 NOTE 3) may prescribe requirements (either generally or in relation to a prescribed class of medicinal product or activity) with which the holder of a wholesale dealer's licence must comply, and which are to have effect as if they were provisions of the licence: 1968 Act s 8(3E) (added by SI 2005/2789).

NOTE 1--SI 1990/566 amended SI 2005/2745.

NOTE 5--1968 Act s 131(5) further amended: National Health Service (Consequential Provisions) Act 2006 Sch 1 para 44.

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48. Prohibitions as to specified medicinal products.

Where it appears to them to be necessary to do so in the interests of safety¹, the appropriate ministers² may by order³: (1) prohibit the sale, supply or importation⁴ of medicinal products⁵ of any description, or falling within any class, specified in the order, or designate⁶ particular medicinal products and prohibit their sale, supply or importation⁷; and (2) prohibit the sale, supply or importation of animal feeding stuffs⁸ in which medicinal products of any description, or falling within any class, specified in the order have been incorporated, or designate⁹ particular animal feeding stuffs in which medicinal products have been incorporated and prohibit their sale, supply or importation¹⁰. Unless in their opinion it is essential to make such an order with immediate effect to avoid serious danger to health whether of human beings or of animals¹¹, the appropriate ministers must, before making an order, consult the appropriate committee¹².

Any person who contravenes such an order is guilty of an offence¹³ and is liable to a penalty¹⁴. Where a medicinal product is sold, supplied or imported in contravention of such an order, any person who, otherwise than for the purpose of performing or exercising a duty or power imposed or conferred by or under the Medicines Act 1968, is in possession of it, knowing or having reasonable cause to suspect that it was sold, supplied or imported in contravention of the order, is guilty of an offence¹⁵ and is liable to a penalty¹⁶.

1 As to considerations of safety see PARA 15 note 10 ante.

2 For the meaning of 'the appropriate ministers' see PARA 3 ante.

3 As to the making of orders see PARA 5 ante. In relation to the making of regulations and orders, the knowledge of civil servants cannot be imputed to ministers, and ministers must know or be told enough to ensure that nothing that it is necessary, because legally relevant, for them to know is left out of account, although this does not mean that they must know everything that is relevant; what it is relevant for them to know is enough to enable them to make an informed judgment: *R (on the application of National Association of Health Stores) v Secretary of State for Health* [2005] EWCA Civ 154, [2005] All ER (D) 324 (Feb). In the absence of any public interest in non-disclosure, a briefing to a minister in respect of a proposed order should be disclosed in litigation contesting the order: *R (on the application of National Association of Health Stores) v Secretary of State for Health* supra at [49] per Sedley LJ. As to disclosure of documents see CIVIL PROCEDURE vol 11 (2009) PARA 749 et seq.

4 For the meaning of 'import' see PARA 7 note 3 ante.

5 For the meaning of 'medicinal product' see PARA 7 ante.

6 In such manner as appears to the ministers sufficient to identify the products in question.

7 Medicines Act 1968 s 62(1)(a). The prohibition may be total, or subject to specified exceptions: see s 62(2).

8 For the meaning of 'animal feeding stuffs' see PARA 7 note 2 ante.

9 See note 6 supra.

10 Medicines Act 1968 s 62(1)(b). The prohibition may be total, or subject to specified exceptions: see s 62(2).

11 As to the meaning of 'animal' see PARA 3 note 7 ante.

12 Medicines Act 1968 s 62(3) (s 62(3)-(5) amended, and s 62(7) substituted, by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 8, Sch 1 para 12). For the meaning of 'the appropriate committee'

see PARA 15 note 5 ante. Where an order is made without such prior consultation it does not have effect after the end of a specified period not exceeding three months, although a further order may be made: see the Medicines Act 1968 s 62(4) (as so amended). For the meaning of 'month' see PARA 22 note 15 ante. Unless an immediate order is essential, the ministers must also consult organisations representing interests likely to be affected substantially (see s 129(6); and PARA 5 ante); these organisations may then give notice of their desire to be heard by or make written representations to the appropriate committee (see s 62(5), (6) (s 62(5) as so amended)). The ministers must take into account the advice of the appropriate committee: see s 62(5), s 129(7) (s 62(5) as so amended). If an order is made and either the appropriate committee has not considered the proposal to make the order, or the order is made contrary to the advice of the appropriate committee, the order must include a statement of the fact that it has been so made: s 62(7) (as so substituted).

As to the orders that have been made under s 62 (as amended) see the Medicines (Bal Jivan Chamcho Prohibition) (No 2) Order 1977, SI 1977/670 (amended by SI 1990/2487; SI 1997/856); the Medicines (Prohibition of Non-medicinal Antimicrobial Substances) Order 1977, SI 1977/2131 (amended by SI 1990/2487; SI 1992/2684); the Medicines (Chloroform Prohibition) Order 1979, SI 1979/382 (amended by SI 1980/263; SI 1989/1184; SI 1990/2487); the Animals and Animal Products (Examination for Residues and Maximum Residue Limits) Regulations 1997, SI 1997/1729 (amended by SI 2001/3590; SI 2004/147); the Prescription Only Medicines (Human Use) Order 1997, SI 1997/1830 (amended by SI 1997/2044; SI 1998/108; SI 1998/1178; SI 1998/2081; SI 1999/1044; SI 1999/3463; SI 2000/1917; SI 2000/2899; SI 2000/3231; SI 2001/2777; SI 2001/2889; SI 2001/3942; SI 2002/2469; SI 2003/696; SI 2003/1590; SI 2003/2915; SI 2004/2; SI 2004/1031; SI 2004/1189; SI 2004/1771; SI 2004/2693; SI 2005/765; SI 2005/848; SI 2005/1507; SI 2005/2759); the Medicines (Veterinary Products) (Prescription Only) Order 2001, SI 2001/1646; the Medicines (Aristolochia and Mu Tong etc) (Prohibition) Order 2001, SI 2001/1841 (amended by SI 2005/2750); and the Medicines for Human Use (Kava-kava) (Prohibition) Order 2002, SI 2002/3170 (amended by SI 2005/2750).

As to the prohibition of the sale or supply of specified medicinal products except in a registered pharmacy and in accordance with a practitioner's prescription see the Medicines Act 1968 s 60 (as amended); and PARA 143 post.

13 Ibid s 67(2).

14 See *ibid* s 67(4) (amended by virtue of the Magistrates' Courts Act 1980 s 32(2)). The penalty on summary conviction is a fine not exceeding the prescribed sum, or on conviction on indictment is a fine or imprisonment for a term not exceeding two years or both: Medicines Act 1968 s 67(4)(a), (b) (as so amended). As to the prescribed sum see PARA 32 note 3 ante.

15 Ibid s 67(3).

16 Ibid s 67(4) (as amended: see note 14 *supra*). The penalty on summary conviction is a fine not exceeding the prescribed sum, and on conviction on indictment is a fine or imprisonment for a term not exceeding two years or both: s 67(4)(a), (b) (as so amended).

UPDATE

48 Prohibitions as to specified medicinal products

NOTE 5--See Case C-141/07 *Re Supply of Medicines by Pharmacies to Nearby Hospitals: EC Commission v Germany* [2008] 3 CMLR 1479, ECJ (geographical restriction on supply of medicinal products to hospitals justified on grounds of protection of public health).

NOTE 12--SI 1977/2131 amended, SI 2001/1646 revoked: SI 2005/2745. SI 1997/1729 further amended: SI 2005/2626 (England), SI 2005/3254 (Wales), SI 2006/755, SI 2009/1925. SI 1997/1830 further amended: SI 2005/2626 (England), SI 2005/3324, SI 2005/3254 (Wales), SI 2006/562, SI 2006/915, SI 2006/2807, SI 2007/2178, SI 2007/3101, SI 2008/464, SI 2008/1161, SI 2009/1165, SI 2009/3062. SI 1977/670, SI 2001/1841, SI 2002/3170 further amended: SI 2008/548.

See also the Medicines for Human Use (Prohibition) (Senecio and Miscellaneous Amendments) Order 2008, SI 2008/548.

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(iv) Exemptions

49. Special exemptions.

The product licence provisions¹ do not apply to anything done in accordance with an animal test certificate²; nor do those provisions or the restrictions imposed in respect of medicinal tests on animals³ apply to anything done in relation to a medicinal product⁴ for the purposes of a medicinal test on animals⁵ which is to be carried out wholly outside the United Kingdom⁶, unless the product falls within a class specified in an order⁷ made by the agriculture ministers⁸.

The manufacturer's licence provisions⁹ do not apply to the manufacture¹⁰ or assembly¹¹ of any medicinal product for the sole purpose of its being administered¹² by way of a medicinal test on animals, or of its being sold, supplied or exported¹³ for the sole purpose of its being so administered, unless the product falls within a class of medicinal products specified in an order made by the agriculture ministers¹⁴.

The appropriate ministers¹⁵ may provide by order that the licensing provisions¹⁶ are to have effect subject to such exemptions¹⁷ as they may specify in the order¹⁸.

1 Ie the provisions of the Medicines Act 1968 s 7 (as amended): see PARA 44 ante.

2 Ibid s 35(1) (s 35(1), (4) amended by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 54, Sch 10 Pt 1 para 7(1), (2)). For the meaning of 'animal test certificate' see PARA 127 note 14 post.

3 Ie the Medicines Act 1968 s 32(1): see PARA 127 post.

4 For the meaning of 'medicinal product' see PARA 7 ante.

5 For the meaning of 'medicinal test on animals' see PARA 126 post.

6 For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

7 Ie made for the purposes of the Medicines Act 1968 s 35(2)(b): see the text to notes 9-14 infra.

8 Ibid s 35(4) (as amended: see note 2 supra). For the meaning of 'the agriculture ministers' see PARA 3 note 5 ante. See also note 14 infra.

9 Ie ibid s 8(2): see PARA 46 ante.

10 As to the meaning of 'manufacture' see PARA 7 note 2 ante.

11 For the meaning of 'assembly' see PARA 6 note 8 ante.

12 As to the meaning of 'administer' see PARA 7 note 2 ante.

13 For the meaning of 'export' see PARA 7 note 4 ante.

14 Medicines Act 1968 s 35(2)(b). No class of medicinal products may be specified in such an order unless it appears to the agriculture ministers to be requisite to do so for securing that this exemption does not apply to medicinal products consisting wholly or partly of substances the purity or potency of which cannot, in their opinion, be adequately tested by chemical means: s 35(3). For the meaning of 'substance' see PARA 7 note 1 ante. As to the making of orders see PARA 5 ante.

15 For the meaning of 'the appropriate ministers' see PARA 3 ante.

16 le the Medicines Act 1968 ss 7, 8 (both as amended): see PARAS 44, 46-47 ante.

17 le additional to those conferred by *ibid* ss 9-14 (ss 9-11, 14 as amended) (see PARAS 50-54 post): s 15(1).

18 *Ibid* s 15(1). As to the orders that have been made under s 15(1) see the Medicines (Exemption from Licences) (Food and Cosmetics) Order 1971, SI 1971/1410 (amended by SI 1973/2079); the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971, SI 1971/1450 (amended by SI 1972/1200; SI 1989/1184; SI 1989/2323); the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972, SI 1972/41200 (amended by SI 1974/498; SI 1977/161; SI 1989/2323; SI 1994/2987; SI 2004/1031); the Medicines (Exemption from Licences) (Ingredients) Order 1974, SI 1974/1150; the Medicines (Exemption from Licences) (Wholesale Dealing in Confectionery) Order 1975, SI 1975/762 (amended by SI 1994/3144); the Medicines (Exemption from Licences) (Medicinal Tests on Animals) Order 1977, SI 1977/161; the Medicines (Exemption from Licences) (Assembly) Order 1979, SI 1979/1114 (see PARA 46 ante); the Medicines (Contact Lens Fluids and Other Substances) (Exemption from Licences) Order 1979, SI 1979/1585 (amended by SI 1979/1745; SI 2002/3135; SI 2005/848) (see PARA 46 ante); the Medicines (Exemption from Licences) (Importation) Order 1984, SI 1984/673 (amended by SI 2005/2754); the Medicines (Veterinary Drugs) (Exemption from Licences) (Importation) Order 1986, SI 1986/228 (amended by SI 1994/3142); the Medicines (Exemption from Licences) (Wholesale Dealing) Order 1990, SI 1990/566 (amended by SI 1994/3142; SI 1994/3144); the Medicines (Exemption from Licensing) (Radiopharmaceuticals) Order 1992, SI 1992/2844; and the Medicines for Human Use (Prescribing) Order 2005, SI 2005/765 (amended by SI 2005/1507) (see PARA 51 post).

Any exemption conferred by such an order may be conferred subject to specified conditions or limitations: Medicines Act 1968 s 15(2). As to such exemptions see further PARA 50 et seq post.

UPDATE

49 Special exemptions

NOTE 18--SI 1971/1450, SI 1972/1200, SI 1974/1150, SI 1990/566 amended, SI 1977/161, SI 1986/228 revoked: SI 2005/2745. See also Medicines (Exemptions and Miscellaneous Amendments) Order 2009, SI 2009/3062, art 2.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(4) LICENCES AND LICENSING/(iv) Exemptions/50. Exemptions for practitioners.

50. Exemptions for practitioners.

The licensing provisions¹ do not apply to anything done by a doctor² or dentist³ which consists of manufacturing⁴ or assembling⁵ or procuring the manufacture or assembly of a medicinal product⁶ specially prepared or specially imported⁷ by him or to his order for administration⁸ to a particular patient of his⁹ (or, where he has been requested to carry out any of these operations by another doctor or dentist, to a particular patient of that other doctor or dentist¹⁰), or of selling or supplying or procuring the sale or supply of the product to that patient or to a person under whose care that patient is¹¹ (or, where he has been so requested by another doctor or dentist, to that other doctor or dentist¹²).

Subject to exceptions relating to vaccines, plasma, sera and veterinary medicinal products¹³, the licensing provisions do not apply to anything done by a veterinary surgeon or veterinary practitioner which consists of manufacturing or assembling or procuring the manufacture or assembly of a medicinal product specially prepared for administration to a particular animal or herd which is under his care¹⁴ (or, where he has been requested to carry out any of these operations by another veterinary surgeon or veterinary practitioner, to a particular animal or herd under the care of that other veterinary surgeon or veterinary practitioner¹⁵), or of selling or supplying or procuring the sale or supply of the product to a person having the possession or control of that animal or herd¹⁶ (or, where he has been so requested by another veterinary surgeon or veterinary practitioner, to that other surgeon or practitioner¹⁷).

1 le the Medicines Act 1968 ss 7, 8 (as amended): see PARAS 44, 46-47 ante.

2 For the meaning of 'doctor' see PARA 7 note 10 ante.

3 For the meaning of 'dentist' see PARA 7 note 10 ante.

4 As to the meaning of 'manufacture' see PARA 7 note 2 ante.

5 For the meaning of 'assemble' see PARA 6 note 8 ante.

6 For the meaning of 'medicinal product' see PARA 7 ante.

7 For the meaning of 'import' see PARA 7 note 3 ante. For special exemptions relating to imports see PARA 54 post.

8 As to the meaning of 'administer' see PARA 7 note 2 ante.

9 Medicines Act 1968 s 9(1)(a).

10 Ibid s 9(1)(b).

11 Ibid s 9(1)(a).

12 Ibid s 9(1)(b).

13 Ibid s 9(2) does not exempt from the restrictions imposed by ss 7, 8 (as amended) (including s 7 as extended by s 43 (see PARA 45 ante)) anything done by a veterinary surgeon or veterinary practitioner: (1) in relation to a vaccine specially prepared for administration to poultry (s 9(3)(a)); (2) in relation to any other vaccine unless it is specially prepared for administration to the animal from which it is derived (s 9(3)(b)); (3) in relation to plasma or a serum, unless it is specially prepared for administration to one or more animals in the herd from which it is derived (s 9(3)(c)); or (4) in relation to a ready-made veterinary medicinal product as defined in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) on the approximation of the laws of the

member states relating to veterinary medicinal products, art 1.2 (Medicines Act 1968 s 9(3)(d) (added by the Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994, SI 1994/2987, reg 10); Medicines Act 1968 s 132(1) (amended by the Medicines Act 1968 (Amendment) (No 2) Regulations 1992, SI 1992/3271, reg 3)). For the meanings of 'veterinary surgeon' and 'veterinary practitioner' see PARA 7 note 10 ante. 'Poultry' means domestic fowls, turkeys, geese, ducks, guinea-fowls, pigeons, pheasants and partridges; and 'herd' includes a flock: Medicines Act 1968 s 132(1). As to the meaning of 'animal' see PARA 3 note 7 ante.

A further exception to s 9(2) is made by the Medicines (Exemptions from Licences) (Carbadox and Olaquinox) Order 1987, SI 1987/2217: see PARA 55 post.

14 Medicines Act 1968 s 9(2)(a).

15 Ibid s 9(2)(b).

16 Ibid s 9(2)(a).

17 Ibid s 9(2)(b).

UPDATE

50 Exemptions for practitioners

NOTE 13--SI 1987/2217 revoked: SI 2005/2745.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(4) LICENCES AND LICENSING/(iv) Exemptions/51. Exemptions for pharmacists.

51. Exemptions for pharmacists.

Subject to exceptions relating to vaccines, plasma and sera¹, the licensing provisions² do not apply to:

- 65 (1) the assembly³ of a medicinal product⁴; or
- 66 (2) the preparation or dispensing in accordance with a practitioner's prescription of a medicinal product⁵; or
- 67 (3) the preparation of a stock of medicinal products to be so dispensed⁶,

where that assembly, preparation or dispensing is done by or under the supervision of a pharmacist⁷ in a registered pharmacy, hospital⁸ or health centre⁹.

Further exemptions apply to things done by or under the supervision of a pharmacist in a registered pharmacy¹⁰.

In those circumstances, the licensing provisions do not apply to the preparation or dispensing of a medicinal product¹¹ or to the preparation of a stock of medicinal products to be dispensed¹²: (a) where the product is prepared or dispensed in accordance with a specification furnished by the person to whom the product is to be sold or supplied, and it is prepared or dispensed for administration to that person or to a person under his care¹³ or to an animal or herd in his possession or under his control¹⁴; or (b) where the product is prepared or dispensed for administration to a person who has requested, or on whose behalf a request has been made to, the pharmacist to do so in accordance with the pharmacist's own judgment as to the treatment required, and the person is present in the pharmacy at the time the request is made¹⁵.

In similar circumstances¹⁶: (i) the product licence provisions¹⁷ do not apply to the preparation or dispensing of a medicinal product which has not been ordered by another person¹⁸, or advertised¹⁹, where it is prepared for retail sale or supply in circumstances corresponding to retail sale at the pharmacy at which it is prepared²⁰; (ii) the manufacturer's licence provisions²¹ do not apply to the preparation of a medicinal product for retail sale or supply in circumstances corresponding to retail sale at the pharmacy at which it is prepared²²; and (iii) the wholesale dealer's licence provisions²³ do not apply to wholesale dealing²⁴ which constitutes no more than an inconsiderable part of the business carried on by the pharmacist in that pharmacy²⁵.

1 The exemption does not apply: (1) to a vaccine specially prepared for administration to poultry (Medicines Act 1968 s 10(2)); or (2) to any other vaccine or any plasma or serum prepared or dispensed for administration to an animal or herd unless: (a) the vaccine is specially prepared for administration to the animal from which it is derived (s 10(2)(a)); or (b) the plasma or serum is specially prepared for administration to one or more animals in the herd from which it is derived (s 10(2)(b)), and (in either case) it is so prepared in accordance with a prescription given by a veterinary surgeon or veterinary practitioner (s 10(2)). As to the meaning of 'administer' see PARA 7 note 2 ante. For the meanings of 'poultry' and 'herd' see PARA 50 note 13 ante. As to the meaning of 'animal' see PARA 3 note 7 ante. For the meanings of 'veterinary surgeon' and 'veterinary practitioner' see PARA 7 note 10 ante.

2 *le ibid* ss 7, 8 (both as amended): see PARAS 44, 46-47 ante.

3 For the meaning of 'assembly' see PARA 6 note 8 ante. Where the assembly takes place in a registered pharmacy, the business in medicinal products carried on there must be restricted to retail sale or supply in circumstances corresponding to retail sale and the assembling must be done with a view to such sale or supply either there or at another such pharmacy forming part of the same retail pharmacy business: *ibid* s 10(1)(b)(i) (s 10(1)(b), (4)(b) amended, and s 10(1)(b)(i), (ii), (5)-(8) added, by the Medicines (Retail Pharmacists--

Exemptions from Licensing Requirements) Order 1971, SI 1971/1445, art 3). 'Registered pharmacy' means premises for the time being entered in the register of premises required to be kept under the Medicines Act 1968 s 75 (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 902): ss 74(1), 132(1) (s 74(1) amended by the Statute Law (Repeals) Act 1993). As to the meaning of 'business' see PARA 7 note 11 ante. For the meaning of 'medicinal product' see PARA 7 ante. As to references to retail sale see PARA 7 note 12 ante. 'Retail pharmacy business' means a business (not being a professional practice carried on by a practitioner) which consists of or includes the retail sale of medicinal products other than medicinal products on a general sale list (see PARA 133 post) (whether medicinal products on such a list are sold in the course of that business or not): Medicines Act 1968 s 132(1). For the meaning of 'practitioner' see PARA 7 note 10 ante.

Further, the medicinal product must not have been the subject of an advertisement: s 10(1)(b)(ii) (as so added). 'Advertisement' has the meaning assigned by s 92 (as amended) (see PARA 157 post), except that it does not include words inscribed on the product or its container or package: s 10(8) (as so added). For the meanings of 'container' and 'package' see PARA 152 note 4 post.

4 Ibid s 10(1)(b) (as amended: see note 3 supra). See also note 10 infra.

5 Ibid s 10(1)(a). See also note 10 infra.

6 Ibid s 10(4)(b) (as amended: see note 3 supra). However, the stock must be prepared with a view to retail sale or to supply in circumstances corresponding to retail sale and the preparation must be done with a view to such sale or supply either there or at any other registered pharmacy forming part of the same retail pharmacy business: s 10(4)(b) (as so amended).

7 For the meaning of 'pharmacist' see PARA 46 note 10 ante.

8 As to the meaning of 'hospital' see PARA 7 note 9 ante.

9 Medicines Act 1968 s 10(1), (4). See also note 10 infra. 'Health centre' means a health centre maintained under the National Health Service Act 1977 ss 2, 3 (see HEALTH SERVICES vol 54 (2008) PARA 10 et seq): Medicines Act 1968 s 132(1) (definition amended by the National Health Service Act 1977 s 129, Sch 15 para 50).

The licensing restrictions also do not apply to anything which is done in a registered pharmacy, a hospital or a health centre and is done there by or under the supervision of a pharmacist and consists of: (1) preparing or dispensing a medicinal product in accordance with a prescription given by a supplementary prescriber (Medicines for Human Use (Prescribing) Order 2005, SI 2005/765, art 2(1)(a)); or (2) procuring the preparation or dispensing of a medicinal product in accordance with a prescription given by a supplementary prescriber (art 2(1)(b)). 'Medicinal product' includes any article or substance in respect of which the Medicines Act 1968 s 58 (see PARA 140 post) has effect by virtue of an order made under s 104 (see PARA 9 ante), but does not include a medicinal product which is a veterinary drug, or an article or substance in respect of which s 58 has such effect where that article or substance is only to be administered to animals: Medicines for Human Use (Prescribing) Order 2005, SI 2005/765, art 1(4). For the meanings of 'animal' and 'veterinary drug' see PARA 3 note 7 ante. 'Supplementary prescriber' means: (a) a first level nurse; (b) a pharmacist; (c) a registered midwife; (d) a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of the Health Professions Order 2001, SI 2002/254, art 5 (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 325) relating to chiropodists and podiatrists, physiotherapists or radiographers: diagnostic or therapeutic; or (e) a registered optometrist; and against whose name is recorded in the relevant register an annotation or entry signifying that he is qualified to order drugs, medicines and appliances as a supplementary prescriber: Medicines for Human Use (Prescribing) Order 2005, SI 2005/765, art 1(4) (definition amended by SI 2005/1507). 'First level nurse' means a person registered in Sub-Part 1 of the Nurses' Part of the register maintained by the Nursing and Midwifery Council under the Nursing and Midwifery Order 2001, SI 2002/253, art 5 (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 717); and 'registered midwife' means a person registered in the Midwives' Part of that register: Medicines for Human Use (Prescribing) Order 2005, SI 2005/765, art 1(4). 'Registered optometrist' means a person whose name is entered in the register of optometrists maintained under the Opticians Act 1989 s 7(a) (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 838): Medicines for Human Use (Prescribing) Order 2005, SI 2005/765, art 1(4) (definition amended by SI 2005/1507). 'Relevant register' means: (i) in relation to a first level nurse or registered midwife, the register maintained by the Nursing and Midwifery Council under the Nursing and Midwifery Order 2001, SI 2002/253, art 5; (ii) in relation to a pharmacist, the register maintained in pursuance of the Pharmacy Act 1954 s 2(1) (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 888); (iii) in relation to a person whose name is registered in the register maintained by the Health Professions Council in pursuance of the Health Professions Order 2001, SI 2002/254, art 5, that register; and (iv) in relation to a registered optometrist, the register of optometrists maintained under the Opticians Act 1989 s 7(a): Medicines for Human Use (Prescribing) Order 2005, SI 2005/765, art 1(4) (definition amended by SI 2005/1507).

10 Medicines Act 1968 s 10(3), (4). However, the provisions of s 10(1)-(6) (as amended) do not have effect so as to exempt from the restrictions imposed by ss 7, 8 (as amended) anything done in a registered pharmacy by or under the supervision of a pharmacist in relation to a ready-made veterinary medicinal product as defined in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) on the approximation of the laws of the member states

relating to veterinary medicinal products, art 1.2: Medicines Act 1968 s 10(6A) (added by the Medicines (Restrictions on the Administration of Veterinary Medicinal Products) Regulations 1994, SI 1994/2987, reg 11).

11 Medicines Act 1968 s 10(3).

12 Ibid s 10(4)(b). See also note 6 supra.

13 Ibid s 10(3)(a). See also note 10 supra.

14 Ibid s 10(3)(b). In this case the product must not be a vaccine, plasma or a serum: see s 10(3)(b). See also note 10 supra.

15 Ibid s 10(4)(a). See also note 10 supra.

16 Ie where anything is done by or under the supervision of a pharmacist in a registered pharmacy: ibid s 10(5)-(7) (as added: see note 3 supra).

17 Ie ibid s 7 (as amended): see PARA 44 ante.

18 Ibid s 10(5)(a) (as added: see note 3 supra). See also note 10 supra.

19 Ibid s 10(5)(c) (as added: see note 3 supra). See also note 10 supra.

20 Ibid s 10(5)(b) (as added: see note 3 supra). See also note 10 supra.

21 Ie ibid s 8(2): see PARA 46 ante.

22 Ibid s 10(6) (as added: see note 3 supra). See also note 10 supra.

23 Ie ibid s 8(3) (as substituted and amended) and s 8(3A) (as added and amended): see PARA 47 ante.

24 As to the meaning of 'wholesale dealing' see PARA 47 note 5 ante.

25 Medicines Act 1968 s 10(7) (as added (see note 3 supra); and amended by the Medicines Act 1968 (Amendment) Regulations 1993, SI 1993/834, reg 3).

UPDATE

51 Exemptions for pharmacists

TEXT AND NOTES--The following provisions are not yet in force. The health ministers may make regulations prescribing conditions which must be complied with if a thing is to be considered for the purposes of the 1968 Act s 10 as done under the supervision of a pharmacist: s 10(7A) (added by Health Act 2006 s 26(1)). Conditions prescribed under the 1968 Act s 10(7A) may relate to supervision in the case where the pharmacist is not at the place where the thing is being done, and in that case the thing is not to be so considered if no such conditions are prescribed: s 10(7B) (as so added). In any case, compliance with any applicable conditions is sufficient for the thing to be so considered: s 10(7C) (as so added).

NOTE 9--Definition of 'relevant register' further amended: SI 2007/289.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(4) LICENCES AND LICENSING/(iv) Exemptions/52. Exemptions for nurses and midwives.

52. Exemptions for nurses and midwives.

The manufacturer's licence and wholesale dealer's licence provisions¹ do not apply to the assembly² of any medicinal products³ by a person in the course of that person's profession as a registered nurse or a registered midwife⁴.

1 Ie the Medicines Act 1968 s 8 (as amended): see PARAS 46-47 ante.

2 For the meaning of 'assembly' see PARA 6 note 8 ante.

3 For the meaning of 'medicinal product' see PARA 7 ante.

4 Medicines Act 1968 s 11(1) (amended by the Nurses, Midwives and Health Visitors Act 1979 s 23, Sch 7 para 14 (a), Sch 8; and the Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004, SI 2004/1771, art 3, Schedule para 10(a)). As to the registration of nurses and midwives see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 716 et seq.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(4) LICENCES AND LICENSING/(iv) Exemptions/53. Exemptions for herbal remedies.

53. Exemptions for herbal remedies.

The licensing provisions¹ do not apply to the sale, supply, manufacture² or assembly³ of any herbal remedy⁴ produced only by drying, crushing or comminuting plants⁵, provided that the remedy is, or is to be, sold or supplied: (1) under a designation which only specifies the plant or plants and the process and does not apply any other name to the remedy⁶; and (2) without any written⁷ recommendation, whether by means of a labelled container⁸ or package⁹ or a leaflet¹⁰ or in any other way, as to its use¹¹.

Where a herbal remedy is sold, supplied, manufactured or assembled in the course of a business¹², the licensing provisions do not apply to those processes if the remedy is manufactured or assembled on premises of which the person carrying on the business is the occupier and which he is able to close so as to exclude the public¹³, and he sells or supplies the remedy for administration¹⁴ to a person who has requested or on whose behalf a request has been made to the person carrying on the business to use his own judgment as to the treatment required¹⁵.

1 The Medicines Act 1968 ss 7, 8 (both as amended): see PARAS 44, 46-47 ante.

2 As to the meaning of 'manufacture' see PARA 7 note 2 ante.

3 For the meaning of 'assembly' see PARA 6 note 8 ante.

4 For the meaning of 'herbal remedy' see PARA 7 note 14 ante.

5 As to the meaning of 'plant' see PARA 7 note 14 ante.

6 Medicines Act 1968 s 12(2)(a).

7 For the meaning of 'written' see PARA 21 note 4 ante.

8 For the meanings of 'label' and 'container' see PARA 152 note 4 post.

9 For the meaning of 'package' see PARA 152 note 4 post.

10 As to the meaning of 'leaflet' see PARA 153 note 5 post.

11 Medicines Act 1968 s 12(2)(b).

12 As to the meaning of 'business' see PARA 7 note 11 ante.

13 Medicines Act 1968 s 12(1)(a).

14 As to the meaning of 'administer' see PARA 7 note 2 ante.

15 Medicines Act 1968 s 12(1)(b). The person to whom the remedy is to be administered must be present when the request is made: s 12(1)(b).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(4) LICENCES AND LICENSING/(iv) Exemptions/54. Exemptions for imports and re-exports.

54. Exemptions for imports and re-exports.

The prohibition on importing¹ a medicinal product² except in accordance with a product licence³ does not apply where the product is imported for administration⁴ to the importer himself or to any member of his household or where the product is specially imported by or to the order of a doctor⁵ or dentist⁶ for administration to a particular patient of his⁷. The ministers⁸ may by order⁹ specify additional circumstances in which this prohibition is not to apply¹⁰, and have exercised this power to exempt from the prohibition: (1) the importation of medicinal products (other than specified products) which are to be re-exported without any change in their form or their manner of assembly¹¹; and (2) the importation of medicinal products where the arrangements for their manufacture or assembly in the United Kingdom¹² have been seriously impeded by specified emergency circumstances¹³.

The licensing provisions generally¹⁴ do not apply to the exportation¹⁵, or the sale or offer for sale for the purposes of exportation, of any imported medicinal product if it is, or is to be, exported in the form in which it was imported¹⁶ and without any change in the way in which it was assembled on being imported¹⁷.

1 For the meaning of 'import' see PARA 7 note 3 ante.

2 For the meaning of 'medicinal product' see PARA 7 ante.

3 The prohibition imposed by the Medicines Act 1968 s 7(3): see PARA 44 ante. For the meaning of 'product licence' see PARA 44 note 5 ante.

4 As to the meaning of 'administer' see PARA 7 note 2 ante.

5 For the meaning of 'doctor' see PARA 7 note 10 ante.

6 For the meaning of 'dentist' see PARA 7 note 10 ante.

7 Medicines Act 1968 s 13(1).

8 For the meaning of 'the ministers' see PARA 3 note 3 ante.

9 As to the making of orders see PARA 5 ante. Any exemption conferred by such an order may be conferred either in relation to medicinal products generally or in relation to a specified class of them, and may be conferred subject to specified conditions or limitations: Medicines Act 1968 s 13(3).

10 Ibid s 13(2). In addition to the orders described in the text to notes 11-13 infra, the following orders have been made under this provision: the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972, SI 1972/1200 (amended by SI 1974/498; SI 1977/161; SI 1989/2323; SI 1994/2987; SI 2004/1031); the Medicines (Exemption from Licences) (Ingredients) Order 1974, SI 1974/1150; the Medicines (Exemption from Licences) (Medicinal Tests on Animals) Order 1977, SI 1977/161; the Medicines (Contact Lens Fluids and Other Substances) (Exemption from Licences) Order 1979, SI 1979/1585 (amended by SI 1979/1745; SI 2002/3135; 2005/848) (see PARA 46 ante); the Medicines (Exemption from Licences) (Importation) Order 1984, SI 1984/673 (amended by SI 2005/2754); and the Medicines (Veterinary Drugs) (Exemption from Licences) (Importation) Order 1986, SI 1986/228 (amended by SI 1994/3142).

11 See the Medicines (Importation of Medicinal Products for Re-exportation) Order 1971, SI 1971/1326 (amended by SI 1977/640; SI 1994/3142).

12 For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

13 See the Medicines (Exemption from Licences) (Emergency Importation) Order 1974, SI 1974/316, which applies only to the importation of medicinal products that are already the subject of a product licence of right and where certain conditions as to undertakings, declarations and notifications are satisfied (see art 2(3)). As to licences of right see PARA 12 note 23 ante. The exemption does not apply to certain veterinary drugs: see art 2(4).

14 See the Medicines Act 1968 ss 7, 8 (both as amended): see PARAS 44, 46-47 ante.

15 For the meaning of 'export' see PARA 7 note 4 ante.

16 Medicines Act 1968 s 14(1)(a) (s 14(1) renumbered and amended by the Medicines Act 1968 (Amendment) Regulations 1993, SI 1993/834, reg 4(a)).

17 Medicines Act 1968 s 14(1)(b) (as renumbered and amended: see note 16 supra). However, s 8(3A) (as added) (see PARA 47 ante) applies to the exportation, or the sale for exportation, of any product to which EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) on the Community code relating to medicinal products for human use (as amended) applies if it is, or is to be exported to a member state: s 14(2) (added by the Medicines Act 1968 (Amendment) Regulations 1993, SI 1993/834, reg 4(b); and amended by the Medicines (Codification Amendments Etc) Regulations 2002, SI 2002/236, reg 2(a)(ii)). For the meaning of 'member state' see the European Communities Act 1972 s 1(2), Sch 1 Pt II; and the Interpretation Act 1978 s 5, Sch 1.

UPDATE

54 Exemptions for imports and re-exports

NOTE 10--SI 1972/1200, SI 1974/1150 amended, SI 1977/161, SI 1986/228 revoked: SI 2005/2745.

NOTE 11--SI 1971/1326 amended: SI 2005/2745.

NOTE 13--SI 1974/316 amended: SI 2005/2745.

NOTE 17--For 'member state' read 'an EEA state': 1968 Act s 14(2) (amended by the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005, SI 2005/2789).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(4) LICENCES AND LICENSING/(iv) Exemptions/55. Extending or modifying exemptions.

55. Extending or modifying exemptions.

The appropriate ministers¹ may by order² provide that any of the provisions exempting from the licensing provisions³ things done by doctors, dentists, veterinary surgeons or veterinary practitioners⁴, pharmacists⁵, nurses and midwives⁶, or the provisions exempting herbal remedies⁷, imports and re-exports⁸, are to cease to have effect or are to have effect subject to such exceptions or modifications as may be specified in the order⁹.

1 For the meaning of 'the appropriate ministers' see PARA 3 ante.

2 No order may be made under the Medicines Act 1968 s 15(3) unless a draft of it has been laid before Parliament and approved by a resolution of each House of Parliament: s 15(4). As to the laying of documents before Parliament see PARLIAMENT vol 34 (Reissue) PARA 941. As to the making of orders see PARA 5 ante.

3 le ibid ss 7, 8 (both as amended): see PARAS 44, 46-47 ante.

4 le ibid s 9 (as amended): see PARA 50 ante.

5 le ibid s 10 (as amended): see PARA 51 ante.

6 le ibid s 11 (as amended): see PARA 52 ante.

7 le ibid s 12: see PARA 53 ante.

8 le ibid ss 13, 14 (as amended): see PARA 54 ante.

9 Ibid s 15(3). For orders under s 15(3) see the Medicines (Retail Pharmacists--Exemptions from Licensing Requirements) Order 1971, SI 1971/1445; and the Medicines (Exemption from Licences) (Carbadox and Olaquinox) Order 1987, SI 1987/2217.

UPDATE

55 Extending or modifying exemptions

NOTE 9--SI 1987/2217 revoked: SI 2005/2745.

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(v) Grant and Renewal of Licences

56. Applications for licences.

Any application for the grant of a licence¹ must be made to the licensing authority² and must be made in such form and manner, and must contain, or be accompanied by, such information, documents, samples and other material, as may be prescribed³. The application must indicate the descriptions of medicinal products⁴ in respect of which the licence is required, either by specifying the descriptions of medicinal products in question or by way of an appropriate general classification⁵. Where documents are forwarded to the licensing authority⁶, or documents that constitute a dossier⁷ are forwarded to that authority⁸, such forwarding is deemed to be an application for the grant of a product licence⁹ under the Medicines Act 1968¹⁰. Unless the application expressly provides otherwise, every application for the grant of a licence must be taken to be an application for the grant of a licence for a full period of five years¹¹ from the date of grant¹².

1 I.e. a licence under the Medicines Act 1968 Pt II (ss 6-50) (as amended). As to applications for the grant of marketing authorisations in respect of medicines for human use see PARA 22 ante; and as to applications in respect of veterinary medicinal products see PARA 35 ante.

2 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

3 Medicines Act 1968 s 18(1). 'Prescribed' means prescribed by regulations under the Act: s 132(1). As to the making of regulations see PARA 5 ante. As to the form and manner of, and the material to be contained in, or to accompany, an application for a product, manufacturer's or wholesale dealer's licence see the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Regulations 1971, SI 1971/973 (amended by SI 1972/1201; SI 1975/681; SI 1977/1051; SI 1979/1760; SI 1983/1726; SI 1992/755; SI 1993/2398; SI 1993/2538; SI 1996/2194; SI 2004/1031); the Medicines (Applications for Manufacturer's and Wholesale Dealer's Licences) Regulations 1971, SI 1971/974 (amended by SI 1977/1052; SI 1978/1140; SI 1983/1725; SI 1993/832; SI 2002/236); the Medicines (Renewal Applications for Licences and Certificates) Regulations 1974, SI 1974/832 (amended by SI 1977/180; SI 1982/1789; SI 1992/755; SI 1993/1227; SI 2004/1031); the Medicines (Contact Lens Fluids and Other Substances) (Advertising and Miscellaneous Amendments) Regulations 1979, SI 1979/1760 (amended by SI 2005/848); the Medicines (Veterinary Medicinal Products) (Renewal Applications for Product Licences Subject to Review) Regulations 1993, SI 1993/2399; the Medicines (Applications for Grant of Product Licences--Products for Human Use) Regulations 1993, SI 1993/2538 (amended by SI 1994/3144; SI 1997/654; SI 2002/236; SI 2003/2321; SI 2005/2759); and the Medicines (Veterinary Drugs) (Renewal Applications for Licences and Animal Test Certificates) Regulations 1994, SI 1994/3143 (amended by SI 1996/2194). As to the power of the licensing authority to require further information see PARA 57 post. As to the right of an authorised person to enter premises to verify statements contained in an application see PARA 169 post; and as to the power to inspect and take samples for that purpose see PARA 170 post. Information supplied by the original manufacturer of a drug may be considered on a subsequent application by a manufacturer of a generic version of a drug: *Re Smith Kline & French Laboratories Ltd* [1990] 1 AC 64, sub nom *Smith Kline & French Laboratories Ltd v Licensing Authority* [1989] 1 All ER 578, HL.

4 For the meaning of 'medicinal product' see PARA 7 ante. As to descriptions of medicinal products see PARA 7 note 33 ante.

5 Medicines Act 1968 s 18(2).

6 I.e. EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 17.

7 I.e. for the purposes of EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) on the Community code relating to medicinal products for human use (as amended).

8 I.e. under and in accordance with *ibid* art 28.

9 For the meaning of 'product licence' see PARA 44 note 5 ante.

10 Medicines Act 1968 s 18(3) (substituted by the Medicines (Medicines Act 1968 Amendment) Regulations 1983, SI 1983/1724, reg 4; and amended by the Medicines (Codification Amendments Etc) Regulations 2002, SI 2002/236, reg 2(b)). See also the Medicines Act 1968 (Application to Radiopharmaceutical-associated Products) Regulations 1992, SI 1992/605 (amended by SI 2004/1031; SI 2005/2754).

11 Ie the full period specified in the Medicines Act 1968 s 24(1) (see PARA 69 post) for the duration of licences granted under Pt II (as amended). Any reference in Pt II (as amended) (including a reference implied by virtue of s 24(4) (see PARA 68 note 13 post)) to the grant of a licence otherwise than in accordance with the application is to be construed accordingly: s 24(5).

12 Ibid s 24(5). The date of issue is excluded in computing the period: cf *Goldsmith's Co v West Metropolitan Rly Co* [1904] 1 KB 1, CA; *Stewart v Chapman* [1951] 2 KB 792, [1951] 2 All ER 613, DC. As to fees on applications see the Medicines (Products for Human Use--Fees) Regulations 1995, SI 1995/1116 (amended by SI 1996/683; SI 1998/574; SI 1999/566; SI 2000/592; SI 2000/3031; SI 2001/795; SI 2002/236; SI 2002/542; SI 2003/625; SI 2003/2321; SI 2004/666; SI 2004/1157; SI 2005/1124); and the Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750 (amended by SI 2004/3081).

UPDATE

56 Applications for licences

NOTE 3--SI 1971/974 further amended: SI 2005/2745, SI 2005/2789. SI 1979/1760 further amended: SI 2007/3101. SI 1993/2399 revoked: SI 2005/2745.

NOTE 4--SI 1974/832 revoked, in relation to manufacturer's licences and wholesale dealer's licences in so far as such licences relate to relevant medicinal products, by SI 2005/2789. For these purposes 'relevant medicinal product' means a medicinal product for human use to which the provisions of the Directive apply; the 'Directive' means European Parliament and EC Council Directive 2001/83 on the Community code relating to medicinal products for human use: SI 2005/2789 reg 1.

NOTE 12--SI 1995/1116 replaced: see now the Medicines (Products for Human Use) (Fees) Regulations 2009, SI 2009/389 (amended by SI 2009/3222).

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57. Provision of further information.

Where an application has been made to the licensing authority¹ for a licence², the authority, before determining the application, may request the applicant to furnish such information relating to the application as it may consider requisite³. The authority is not required to determine the application until either the information has been furnished⁴ or it has been shown to its reasonable satisfaction that the applicant is unable to furnish the information⁵.

1 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

2 I.e. under the Medicines Act 1968 Pt II (ss 6-50) (as amended). This provision applies also to applications for an animal test certificate (see PARA 130 post): s 44(1) (amended by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 54, Sch 10 Pt I para 12).

3 Medicines Act 1968 s 44(1). As to applications generally see PARA 56 ante.

4 Ibid s 44(1)(a).

5 Ibid s 44(1)(b).

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58. Factors relevant to determination of product licence application.

In dealing with an application for a product licence¹, the licensing authority² must in particular take into consideration³ the safety⁴ of medicinal products⁵ of each description to which the application relates⁶, the efficacy of the products for the purposes for which the products are proposed to be administered⁷, and the quality of the products according to the specification and the method or proposed method of manufacture⁸ and the provisions proposed for securing that the products as sold or supplied will be of that quality⁹. The considerations of safety and efficacy¹⁰ may¹¹ be left out of account where the application indicates that the purposes for which the licence is required relate exclusively to the exportation¹² of medicinal products¹³. Where the application indicates that the purposes for which the licence is required relate wholly or partly to medicinal products which have been or are to be imported¹⁴, the authority must also take into consideration in particular the methods, standards and conditions of manufacture and may, if it thinks fit, require the production by the applicant of any one or more of: (1) an undertaking by the manufacturer to permit inspection by or on behalf of the authority of the premises where the products are or are to be manufactured and of the manufacturing operations¹⁵; (2) an undertaking by or on behalf of the manufacturer to comply with conditions¹⁶; and (3) a declaration by or on behalf of the manufacturer that the law of the country of manufacture has been or will be complied with¹⁷.

In taking into consideration the efficacy for a particular purpose of medicinal products, the authority must leave out of account any question whether medicinal products of another description would or might be equally or more efficacious for that purpose¹⁸. This does not, however, require the authority, in considering the safety of medicinal products in relation to a purpose for which they are proposed to be administered, to leave out of account any question whether medicinal products of another description, being equally or more efficacious for the purpose, would or might be safer¹⁹.

1 For the meaning of 'product licence' see PARA 44 note 5 ante.

2 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

3 As to the procedure to be followed see the Medicines Act 1968 ss 20-22A (as amended); and PARAS 61-65 post. As to challenges to decisions of the licensing authority see s 107; and PARA 79 post. As to the principles governing the exercise by public bodies of their statutory powers and judicial control thereof see ADMINISTRATIVE LAW vol 1(1) (2001 Reissue) PARAS 16 et seq; JUDICIAL REVIEW.

4 As to considerations of safety see PARA 15 note 10 ante.

5 For the meaning of 'medicinal product' see PARA 7 ante.

6 Medicines Act 1968 s 19(1)(a).

7 Ibid s 19(1)(b). As to the meaning of 'administer' see PARA 7 note 2 ante.

8 As to the meaning of 'manufacture' see PARA 7 note 2 ante.

9 Medicines Act 1968 s 19(1)(c). Section 19(1)-(4) has effect subject to the provisions of Pt II (ss 6-50) (as amended) relating to licences of right (see PARA 12 note 23 ante): s 19(7).

10 See ibid s 19(1)(a), (b); and the text to notes 1-7 supra.

11 Ie if the authority is satisfied that in the circumstances it is reasonable to do so: ibid s 19(4).

12 For the meaning of 'export' see PARA 7 note 4 ante.

13 Medicines Act 1968 s 19(4).

14 For the meaning of 'import' see PARA 7 note 3 ante.

15 Medicines Act 1968 s 19(3)(a).

16 Ibid s 19(3)(b). The conditions are any prescribed conditions or any conditions attached to the licence: s 19(3)(b). For the meaning of 'prescribed' see PARA 56 note 3 ante. As to the regulations made see the Medicines (Manufacturer's Undertakings for Imported Products) Regulations 1977, SI 1977/1038 (amended by SI 1992/2845; SI 1994/3144). These regulations relate, inter alia, to the provision by a manufacturer of staff, premises and plant for the manufacture, handling and storage of medicinal products, quality control, record keeping, and the supply of information to holders of product licences.

17 Medicines Act 1968 s 19(3)(c).

18 Ibid s 19(2).

19 Ibid s 19(2) proviso.

UPDATE

58 Factors relevant to determination of product licence application

NOTE 16--SI 1977/1038 amended: SI 2005/2745.

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59. Factors relevant to determination of manufacturer's licence application.

In dealing with an application for a manufacturer's licence¹, the licensing authority² must in particular take into consideration³ the operations proposed to be carried out in pursuance of the licence⁴, the premises in which those operations are to be carried out⁵, the equipment which is or will be available on the premises for carrying out those operations⁶, the qualifications of the persons under whose supervision those operations will be carried out⁷, and the arrangements made or to be made for securing the safekeeping of, and the maintenance of adequate records in respect of, medicinal products⁸ manufactured⁹ or assembled¹⁰ in pursuance of the licence¹¹.

1 For the meaning of 'manufacturer's licence' see PARA 46 note 7 ante.

2 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

3 As to the procedure to be followed see the Medicines Act 1968 ss 20-22A (as amended); and PARAS 61-65 post. As to challenges to decisions of the licensing authority see s 107; and PARA 79 post. As to the principles governing the exercise by public bodies of their statutory powers and judicial control thereof see ADMINISTRATIVE LAW vol 1(1) (2001 Reissue) PARAS 16 et seq; JUDICIAL REVIEW.

4 Medicines Act 1968 s 19(5)(a).

5 Ibid s 19(5)(b).

6 Ibid s 19(5)(c).

7 Ibid s 19(5)(d).

8 For the meaning of 'medicinal product' see PARA 7 ante.

9 As to the meaning of 'manufacture' see PARA 7 note 2 ante.

10 For the meaning of 'assemble' see PARA 6 note 8 ante.

11 Medicines Act 1968 s 19(5)(e). Section 19(5) has effect subject to the provisions of Pt II (ss 6-50) (as amended) relating to licences of right (see PARA 12 note 23 ante): s 19(7).

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60. Factors relevant to determination of wholesale dealer's licence application.

In dealing with an application for a wholesale dealer's licence¹, the licensing authority² must in particular take into consideration³ the premises on which medicinal products⁴ of the descriptions to which the application relates will be stored⁵, the equipment which is or will be available for storing medicinal products on those premises⁶, the equipment and facilities which are or will be available for distributing medicinal products from those premises⁷, and the arrangements made or to be made for securing the safekeeping of, and the maintenance of adequate records in respect of, medicinal products stored on or distributed from those premises⁸.

1 For the meaning of 'wholesale dealer's licence' see PARA 47 note 12 ante.

2 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

3 As to the procedure to be followed see the Medicines Act 1968 ss 20-22A (as amended); and PARAS 61-65 post. As to challenges to decisions of the licensing authority see s 107; and PARA 79 post. As to the principles governing the exercise by public bodies of their statutory powers and judicial control thereof see ADMINISTRATIVE LAW vol 1(1) (2001 Reissue) PARAS 16 et seq; JUDICIAL REVIEW.

4 For the meaning of 'medicinal product' see PARA 7 ante.

5 Medicines Act 1968 s 19(6)(a).

6 Ibid s 19(6)(b).

7 Ibid s 19(6)(c).

8 Ibid s 19(6)(d). Section 19(6) has effect subject to the provisions of Pt II (ss 6-50) (as amended) relating to licences of right (see PARA 12 note 23 ante); s 19(7).

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61. Grant or refusal of licence.

On any application to the licensing authority¹ for a licence, the authority may grant a licence containing such provisions² as it considers appropriate³, or may refuse to grant a licence if, having regard to the provisions of the Medicines Act 1968 and any Community obligation⁴, it considers it necessary or expedient to do so⁵.

The authority must not refuse to grant a licence on any grounds relating to the price of any product, and must not insert in any licence any provisions as to the price at which any product may be sold, supplied, imported⁶ or exported⁷. Nor may it refuse to grant a licence on any grounds relating to the safety⁸, quality or efficacy of medicinal products⁹ of any description¹⁰ except after consultation with the appropriate committee¹¹.

1 For the meaning of 'the licensing authority' see PARA 43 note 8 ante. As to applications for licences see PARAS 56-60 ante.

2 As to the incorporation of standard provisions in licences see PARA 67 post.

3 Medicines Act 1968 s 20(1)(a). As to the grant or refusal of marketing authorisations for medicines for human use see PARA 23 ante; and as to grant or refusal of marketing authorisations in respect of veterinary medicinal products see PARAS 35-37 ante.

4 For the meaning of 'Community obligation' see the European Communities Act 1972 s 1, Sch 1 Pt II; and the Interpretation Act 1978 s 5, Sch 1.

5 See the Medicines Act 1968 s 20(1)(b) (amended by the Medicines (Medicines Act 1968 Amendment) Regulations 1977, SI 1977/1050, reg 4(3)). See *Wellcome Foundation Ltd v Secretary of State for Social Services* [1988] 2 All ER 684, [1988] 1 WLR 635, HL (trade mark issues irrelevant to such consideration). As to the procedure in a case where the authority proposes to refuse to grant a licence or to grant a licence otherwise than in accordance with the application see PARA 63 post. As to challenges to decisions of the licensing authority see the Medicines Act 1968 s 107; and PARA 79 post. As to the principles governing the exercise by public bodies of their statutory powers and judicial control thereof see ADMINISTRATIVE LAW vol 1(1) (2001 Reissue) PARAS 16 et seq; JUDICIAL REVIEW.

6 For the meaning of 'import' see PARA 7 note 3 ante.

7 Medicines Act 1968 s 20(2). For the meaning of 'export' see PARA 7 note 4 ante.

8 As to considerations of safety see PARA 15 note 10 ante.

9 For the meaning of 'medicinal product' see PARA 7 ante.

10 As to references to medicinal products of any description see PARA 7 note 33 ante.

11 Medicines Act 1968 s 20(3) (amended by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 8, Sch 1 para 1). For the meaning of 'the appropriate committee' see PARA 15 note 5 ante. As to the procedure for such consultation see PARA 62 post. The provisions of the Medicines Act 1968 s 20(2), (3) apply also to applications for the renewal of an animal test certificate: see s 38(5) (as amended); and PARA 131 post.

UPDATE

61 Grant or refusal of licence

TEXT AND NOTES--The licensing authority must either grant or refuse any application for a licence under the 1968 Act Pt II (ss 6-50), before the end of a period of 90 days from the date on which they receive the application: s 20(1A) (s 20(1A)-(1C) added by SI 2005/2789). However, if there are requirements in force under the 1968 Act s 18 (see PARA 56) that apply to the application, s 20(1A) applies only if the requirements have been met: s 20(1B). If a notice under s 44 (see PARA 57) requires the applicant to provide the licensing authority with information, the period specified in s 20(1) stops running when the notice is given, and does not start running again until the licensing authority receives the information, or the applicant has shown to the reasonable satisfaction of the licensing authority why he is unable to provide it: s 20(1C).

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62. Procedure on reference to appropriate committee.

Where the appropriate committee¹ is consulted by the licensing authority² and is of the provisional opinion that, on grounds relating to safety³, quality or efficacy, it may be unable to advise the licensing authority to grant the licence⁴, or may be unable to advise the licensing authority to grant it unless it contains provisions otherwise than in accordance with the application⁵, it must notify the applicant accordingly⁶. A person who has been so notified may, within the time allowed⁷, give notice of his wish to make written⁸ or oral representations to the committee⁹, and the committee must give the applicant an opportunity to make such representations in accordance with the provisions described below¹⁰.

The applicant must provide the committee with his written representations or a written summary of the oral representations he intends to make¹¹, and any documents on which he wishes to rely in support of those representations¹², before the end of the period of six months beginning with the date of his notice, or within such shorter period as the committee may specify in its notification¹³. The applicant may not submit any additional written representations or documents once the time limit or any extension has expired, except with the permission of the committee¹⁴. If the applicant gave notice of his wish to make oral representations, the committee must, after receiving the applicant's written summary and any other documents, arrange for the applicant to make such representations at a hearing before the committee¹⁵. The committee must take into account such representations as are made by the applicant¹⁶ and report its findings and advice to the licensing authority, together with the reasons for its advice¹⁷.

After receiving the report of the committee, the licensing authority must decide whether to grant or refuse the application, or to grant it otherwise than in accordance with the application¹⁸, and take the report into account when making its decision¹⁹. The licensing authority must notify the applicant of its decision²⁰ and the advice given to it by the committee and the reasons for that advice²¹. If (1) the applicant has made representations and the licensing authority has notified him of its decision to refuse to grant the licence, or to grant it otherwise than in accordance with the application²²; or (2) the applicant has not made representations and the licensing authority has notified him of its decision to refuse to grant the licence, or to grant it otherwise than in accordance with the application, on grounds which differ from those relied on in the advice of the appropriate committee²³, then the applicant may, within the time allowed, notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority with respect to the decision²⁴.

1 For the meaning of 'the appropriate committee' see PARA 15 note 5 ante.

2 ie under the Medicines Act 1968 s 20(3) (as amended): see PARA 61 ante. For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

3 As to considerations of safety see PARA 15 note 10 ante.

4 Medicines Act 1968 s 21(1)(a) (s 21 substituted by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 8, Sch 1 para 2).

5 Medicines Act 1968 s 21(1)(b) (as substituted: see note 4 supra).

6 Ibid s 21(1) (as substituted: see note 4 supra). As to the service of notices see PARA 37 note 8 ante. The provisions of s 21 (as substituted) apply also to applications for the renewal of an animal test certificate: see s 38(5) (as amended); and PARA 131 post.

7 'The time allowed' means the period of 28 days beginning with the date of the relevant notification, or such longer period as the licensing authority may allow in any particular case: ibid s 21(12) (as substituted: see note 4 supra); s 132(1) (definition amended by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, Sch 1 para 14(f)).

8 For the meaning of 'written' see PARA 21 note 4 ante.

9 Medicines Act 1968 s 21(2) (as substituted: see note 4 supra).

10 Ibid s 21(3) (as substituted: see note 4 supra).

11 Ibid s 21(4)(a) (as substituted: see note 4 supra).

12 Ibid s 21(4)(b) (as substituted: see note 4 supra).

13 Ibid s 21(4) (as substituted: see note 4 supra). However, if the applicant so requests, the committee may extend the time limit up to a maximum period of 12 months beginning with the date of the applicant's notice: s 21(5) (as so substituted). For the meaning of 'month' see PARA 22 note 15 ante.

14 Ibid s 21(6) (as substituted: see note 4 supra).

15 Ibid s 21(7) (as substituted: see note 4 supra).

16 Ibid s 21(8)(a) (as substituted: see note 4 supra).

17 Ibid s 21(8)(b) (as substituted: see note 4 supra).

18 Ibid s 21(9)(a) (as substituted: see note 4 supra). As to the licensing authority's duty to notify the applicant of the reasons for its decision see PARA 65 post.

19 Ibid s 21(9)(b) (as substituted: see note 4 supra). As to challenges to decisions of the licensing authority see s 107; and PARA 79 post. As to the principles governing the exercise by public bodies of their statutory powers and judicial control thereof see ADMINISTRATIVE LAW vol 1(1) (2001 Reissue) PARAS 16 et seq; JUDICIAL REVIEW.

20 Ibid s 21(10)(a) (as substituted: see note 4 supra).

21 Ibid s 21(10)(b) (as substituted: see note 4 supra).

22 Ibid s 21(11)(a) (as substituted: see note 4 supra).

23 Ibid s 21(11)(b) (as substituted: see note 4 supra).

24 Ibid s 21(11) (as substituted: see note 4 supra). As to the hearing before the person appointed see PARA 64 post.

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63. Procedure in other cases.

When an application is made for the grant of a licence¹ and the appropriate committee² is not consulted³ by the licensing authority⁴, or is so consulted but does not give⁵ a provisional opinion⁶, then, if the licensing authority proposes to refuse to grant the licence⁷ or to grant it otherwise than in accordance with the application⁸, it must notify⁹ the applicant of its proposals and the reasons for them¹⁰. If the applicant is so notified, he may, within the time allowed¹¹, notify the licensing authority of his wish to appear before and be heard by a person appointed by the licensing authority with respect to the proposal¹², or make representations in writing¹³ to the licensing authority with respect to the proposal referred to in the notification¹⁴. If the applicant makes written representations, the licensing authority must take those representations into account before determining the application¹⁵.

1 Medicines Act 1968 s 22(1)(a) (s 22 substituted by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 8, Sch 1 para 3). The Medicines Act 1968 s 22 (as substituted) relates to applications for licences under Pt II (ss 6-50) (as amended): see PARA 56 ante. The provisions of s 22 (as substituted) apply also to applications for the renewal of an animal test certificate: see s 38(5) (as amended); and PARA 131 post.

2 For the meaning of 'the appropriate committee' see PARA 15 note 5 ante.

3 Ie under the Medicines Act 1968 s 20(3) (as amended): see PARA 61 ante.

4 Ibid s 22(1)(b)(i) (as substituted: see note 1 supra). For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

5 Ie in accordance with ibid s 21(1) (as substituted): see PARA 62 ante.

6 Ibid s 22(1)(b)(ii) (as substituted: see note 1 supra).

7 Ibid s 22(2)(a) (as substituted: see note 1 supra).

8 Ibid s 22(2)(b) (as substituted: see note 1 supra).

9 As to the service of notices see PARA 37 note 8 ante.

10 Medicines Act 1968 s 22(2) (as substituted: see note 1 supra).

11 For the meaning of 'the time allowed' see PARA 62 note 7 ante.

12 Medicines Act 1968 s 22(3)(a) (as substituted: see note 1 supra). As to the hearing before the person appointed see PARA 64 post.

13 For the meaning of 'writing' see PARA 21 note 6 ante.

14 Medicines Act 1968 s 22(3)(b) (as substituted: see note 1 supra).

15 Ibid s 22(4) (as substituted: see note 1 supra). As to the licensing authority's duty to notify the applicant of the reasons for its decision see PARA 65 post. As to challenges to decisions of the licensing authority see s 107; and PARA 79 post. As to the principles governing the exercise by public bodies of their statutory powers and judicial control thereof see ADMINISTRATIVE LAW vol 1(1) (2001 Reissue) PARAS 16 et seq; JUDICIAL REVIEW.

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64. Hearing before person appointed.

If the applicant gives notice¹ of his wish to appear before and be heard by a person appointed by the licensing authority², the authority must make that appointment³ and arrange for the applicant to have an opportunity of appearing before that person⁴. The applicant must, before the end of the period of three months⁵ beginning with the date of his notice⁶, provide the person appointed with a written⁷ summary of the oral representations he intends to make⁸ and any documents on which he wishes to rely in support of those representations⁹. The applicant may not submit any additional written representations or documents once the time limit has expired, except with the permission of the person appointed¹⁰. If the applicant fails to comply with the time limit for the submission of his written representations or documents, or any extension of it, he may not appear before or be heard by the person appointed¹¹, and the licensing authority must decide whether to grant or refuse the licence, or to grant it otherwise than in accordance with the application, and notify¹² the applicant accordingly¹³.

At the hearing before the person appointed, both the applicant and the licensing authority may make representations¹⁴. If the applicant so requests the hearing is in public¹⁵. After the hearing the person appointed must provide a report to the licensing authority¹⁶, and the licensing authority must take the report into account and decide whether to grant or refuse the licence, or to grant it otherwise than in accordance with the application, or to confirm or alter its decision, as the case may be¹⁷. The licensing authority must then notify the applicant of its decision¹⁸ and, if the applicant so requests, provide him with a copy of the report of the person appointed¹⁹.

1 le under the Medicines Act 1968 ss 21(11), 22(3) (both as substituted): see PARAS 62-63 ante. As to applications for licences see PARA 56 ante.

2 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

3 Medicines Act 1968 s 22A(1)(a) (s 22A added by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 8, Sch 1 para 3). The person appointed: (1) must not be, or at any time have been, a member of: (a) the Commission on Human Medicines or any of its expert advisory groups (Medicines Act 1968 s 22A(2)(a)(i) (as so added)); (b) the Medicines Commission formerly established under s 2 (repealed) or any of its committees (s 22A(2)(a)(ii) (as so added)); or (c) a committee established under s 4 (as amended), or any sub-committee of such a committee (s 22A(2)(a)(iii) (as so added)); and (2) must not be an officer or servant of any Minister of the Crown (s 22A(2)(b) (as so added)). As to the Commission on Human Medicines, expert advisory groups and committees see PARAS 13-17 ante. As to the former Medicines Commission see PARA 13 note 1 ante. As to Ministers of the Crown see CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARA 354 et seq.

The provisions of the Medicines Act 1968 s 22A (as added) apply also to applications for the renewal of an animal test certificate: see s 38(5) (as amended); and PARA 131 post.

4 Ibid s 22A(1)(b) (as added: see note 3 supra). The licensing authority must give at least 28 days' notice in writing to the applicant of the date, time and place of the hearing by the person appointed, and such notice must request the applicant to state whether he wishes the hearing to be in public: Medicines Act 1968 (Hearings by Persons Appointed) Rules 1986, SI 1986/1761, r 3.

5 For the meaning of 'month' see PARA 22 note 15 ante.

6 If the applicant so requests, the person appointed may, after consulting the licensing authority, extend the time limit up to a maximum period of six months beginning with the date of the applicant's notice: Medicines Act 1968 s 22A(4) (as added: see note 3 supra).

7 For the meaning of 'written' see PARA 21 note 4 ante.

8 Medicines Act 1968 s 22A(3)(a) (as added: see note 3 supra).

9 Ibid s 22A(3)(b) (as added: see note 3 supra). The licensing authority must prepare a list of documents relevant to the hearing and send a copy of the list, together with a copy of each of the documents referred to in it, both to the applicant and to the person appointed, at least 21 days before the date of the hearing: Medicines Act 1968 (Hearings by Persons Appointed) Rules 1986, SI 1986/1761, r 4. Where the documents sent include a report by a person authorised by the authority of an inspection of any premises to which the application relates, the authority must invite the applicant to notify it not less than seven days prior to the date of the hearing whether he intends to dispute any fact contained in that report: r 5(1). Where the applicant gives such notice, the authorised person must attend the hearing and the applicant is entitled to question him about any matter of fact contained in the report: r 5(2).

10 Medicines Act 1968 s 22A(6) (as added: see note 3 supra).

11 Ibid s 22A(5)(a) (as added: see note 3 supra).

12 As to the service of notices see PARA 37 note 8 ante.

13 Medicines Act 1968 s 22A(5)(b) (as added: see note 3 supra). As to the licensing authority's duty to notify the applicant of the reasons for its decision see PARA 65 post. As to challenges to decisions of the licensing authority see s 107; and PARA 79 post. As to the principles governing the exercise by public bodies of their statutory powers and judicial control thereof see ADMINISTRATIVE LAW vol 1(1) (2001 Reissue) PARAS 16 et seq; JUDICIAL REVIEW.

14 Ibid s 22A(7) (as added: see note 3 supra). Subject to the provisions of the Medicines Act 1968 and the other provisions of the Medicines Act 1968 (Hearings by Persons Appointed) Rules 1986, SI 1986/1761, the person appointed may, in his discretion, determine the procedure at the hearing: r 6(1). The applicant may appear in person at the hearing, or may be represented by any other person, and is entitled to call witnesses and to address the person appointed: r 6(2). If the applicant so requests, the hearing by the person appointed must be in public: r 6(4). Any member of the Council on Tribunals in his capacity as such may attend any hearing by a person appointed: s 6(3). As to the Council on Tribunals see ADMINISTRATIVE LAW vol 1(1) (2001 Reissue) PARA 55 et seq. The person appointed may, at the request or with the consent of the applicant, carry out an inspection of any premises to which the application relates (r 8(1)) and if he decides to make such an inspection he must give the applicant reasonable notice of the date and time at which he proposes to do so (r 8(2)). The person appointed may, if he thinks fit, postpone or adjourn any hearing pending before him, or any inspection of premises, and must give the applicant reasonable notice of the date and time of the subsequent hearing or inspection: r 9.

15 Medicines Act 1968 s 22A(8) (as added: see note 3 supra).

16 Ibid s 22A(9)(a) (as added: see note 3 supra).

17 Ibid s 22A(9)(b) (as added: see note 3 supra). See also note 13 supra.

18 Ibid s 22A(10)(a) (as added: see note 3 supra).

19 Ibid s 22A(10)(b) (as added: see note 3 supra). See also the Medicines Act 1968 (Hearings by Persons Appointed) Rules 1986, SI 1986/1761, r 7.

UPDATE

64 Hearing before person appointed

NOTE 14--SI 1986/1761 r 6(3) revoked: SI 2008/2683.

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65. Reasons for decisions.

Where on an application for a licence¹ the licensing authority² refuses to grant a licence³, or grants a licence otherwise than in accordance with the application, and the applicant requests it to state its reasons⁴, the authority must serve⁵ on the applicant a notice stating the reasons for its decision⁶.

1 I.e. a licence under the Medicines Act 1968 Pt II (ss 6-50) (as amended). As to such applications and their consideration see PARAS 56-64 ante.

2 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

3 Medicines Act 1968 s 20(5)(a).

4 Ibid s 20(5)(b).

5 As to the service of notices see PARA 37 note 8 ante.

6 Medicines Act 1968 s 20(5). The provisions of s 20(5) apply also to applications for the renewal of an animal test certificate: see s 38(5) (as amended); and PARA 131 post. As to challenges to the authority's decision see s 107; and PARA 79 post.

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66. Effect of manufacturer's licence.

Subject to the provisions relating to medicinal tests on animals¹ and to certain exceptions², a manufacturer's licence does not have effect so as to authorise the manufacture or assembly of medicinal products of any description for sale or supply to any other person³, or for exportation⁴, unless:

- 68 (1) the holder of the licence⁵ is also the holder of a product licence⁶ which is applicable to medicinal products of that description⁷; or
- 69 (2) the products are manufactured or assembled to the order of a person who is the holder of such a product licence⁸ or, if the products are to be used for the purposes of a clinical trial⁹, the sponsor¹⁰ of that trial¹¹,

and in either case the products are manufactured or assembled in accordance with that product licence¹². Where this provision has effect in relation to medicinal products of any description¹³, and the conditions specified are not fulfilled, the manufacture or assembly of medicinal products of that description for sale or supply to another person, or for exportation, notwithstanding that it complies with the provisions contained in the manufacturer's licence, is deemed to be not in accordance with that licence¹⁴.

1 Medicines Act 1968 s 23(1) (amended by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 54, Sch 10 Pt 1 para 5(1), (2)). As to medicinal tests on animals see PARA 126 et seq post. The Medicines Act 1968 s 23 (as amended) has effect in relation to marketing authorisations for medicines for human use (see the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, reg 9(3); and PARA 20 ante); in relation to veterinary medicinal products (see the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142, reg 18(2); and PARA 34 ante); and in relation to traditional herbal registrations for traditional herbal medicinal products (see the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, SI 2005/2750, reg 10(2); and PARA 230 post).

2 The Medicines Act 1968 s 23(1) (as amended) does not have effect in certain circumstances in relation to the manufacture or assembly of any medicinal product, other than a poultry vaccine, to the order of a practitioner or to the order of a pharmacist in accordance with a prescription given by a practitioner: see s 23(2), (3). As to the meaning of 'manufacture' see PARA 7 note 2 ante. For the meaning of 'assembly' see PARA 6 note 8 ante. For the meaning of 'medicinal product' see PARA 7 ante. For the meaning of 'practitioner' see PARA 7 note 10 ante; and for the meaning of 'pharmacist' see PARA 46 note 10 ante. For the meaning of 'poultry' see PARA 50 note 13 ante.

Where the holder of a manufacturer's licence manufactures or assembles any medicinal product for sale or supply for the purposes of a medicinal test on animals, and an animal test certificate has been issued and certain conditions are fulfilled, then if the conditions specified in s 23(1) (as amended) are not fulfilled s 23 (as amended) has effect as if those conditions were fulfilled in relation to that medicinal product: see s 35(5) (amended by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, Sch 10 Pt 1 para 7(1), (5)). For the meaning of 'manufacturer's licence' see PARA 46 note 7 ante. For the meaning of 'medicinal test on animals' see PARA 126 post. For the meaning of 'animal test certificate' see PARA 127 note 14 post. The provisions of the Medicines Act 1968 s 23(1) (as amended) do not apply to the manufacture or assembly of any medicinal product for sale or supply for the purposes of a medicinal test on animals where that product falls within a class specified by order for the purposes of s 35(2)(b) (see PARA 49 ante): s 35(6).

3 For the meaning of 'person' see PARA 21 note 7 ante.

4 For the meaning of 'export' see PARA 7 note 4 ante.

5 Any reference to the holder of a licence or certificate is to be construed as a reference to the holder of a licence or certificate for the time being in force: Medicines Act 1968 s 132(4).

6 For the meaning of 'product licence' see PARA 44 note 5 ante.

7 Medicines Act 1968 s 23(1)(a).

8 Ibid s 23(1)(b)(i) (s 23(1)(b) substituted by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, Sch 10 Pt 1 para 5(1), (2)).

9 For the meaning of 'clinical trial' see PARA 82 post; definition applied by the Medicines Act 1968 s 23(6) (added by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, Sch 10 Pt 1 para 5(1), (3)).

10 For the meaning of 'sponsor' see PARA 82 post; definition applied by the Medicines Act 1968 s 23(6) (as added: see note 9 supra).

11 Ibid s 23(1)(b)(ii) (as substituted: see note 8 supra).

12 Ibid s 23(1). If by virtue of an order made under s 15 (see PARA 49 ante) an exemption is conferred in respect of the product licence restrictions, but no corresponding exemption is conferred in respect of the manufacturer's licence restrictions, the order may provide that s 23(1) is to have effect subject to such exceptions or modifications as the ministers consider appropriate in the circumstances: s 23(4). For the meaning of 'the ministers' see PARA 3 note 3 ante. See the Medicines (Exemption from Licences) (Special and Transitional Cases) Order 1971, SI 1971/1450 (amended by SI 1972/1200; SI 1989/1184; SI 1989/2323); and the Medicines (Contact Lens Fluids and Other Substances) (Exemption from Licences) Order 1979, SI 1979/1585 (amended by SI 1979/1759; SI 2002/3135; SI 2005/848).

13 As to the description of medicinal products see PARA 7 note 33 ante.

14 Medicines Act 1968 s 23(5).

UPDATE

66 Effect of manufacturer's licence

NOTE 1--SI 1994/3142 revoked: SI 2005/2745.

NOTE 12--SI 1971/1450 amended: SI 2005/2745.

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67. Standard provisions for licences or certificates.

The ministers¹ may prescribe by regulations² standard provisions³ in relation to licences and certificates either generally or in relation to any class of medicinal products⁴. Any standard provisions so prescribed may be incorporated⁵ by the licensing authority⁶ in any licence⁷ or any animal test certificate⁸ granted or issued on or after the date on which the regulations come into operation⁹.

Where standard provisions are prescribed by such regulations¹⁰, or where after such provisions have been so prescribed they are amended by, or superseded by new standard provisions prescribed by, subsequent regulations¹¹, then, as from the end of the period of three months¹² from the date on which the relevant regulations¹³ come into operation, the operative standard provisions¹⁴ are deemed to be incorporated, except in certain circumstances¹⁵, in any licence or animal test certificate which is in force at the end of that period in so far as, in accordance with the relevant regulations, the operative standard provisions are applicable to medicinal products of any description to which that licence or certificate relates¹⁶.

At any time after the relevant regulations are made and before the end of the period of three months from the date on which they come into operation, the holder¹⁷ of any licence or certificate may apply to the authority to direct¹⁸ that the operative standard provisions are not to be deemed to be incorporated in that licence or certificate¹⁹, or that the operative standard provisions must be deemed to be incorporated subject to such exceptions or modifications as may be specified in the application²⁰. If the authority proposes to refuse to give a direction in accordance with the application, then, before determining the application, it must afford to the applicant an opportunity of appearing before, and being heard by, a person appointed for the purpose by the authority, or of making written²¹ representations to the authority with respect to the proposals²². If the authority then determines to refuse to give a direction it must serve²³ on the applicant a notice stating the reasons for its decision²⁴. Where such an application is made, the operative standard provisions are not to be deemed to be incorporated in the licence or certificate before the authority has made a decision²⁵, and if an application is made to the High Court²⁶ with respect to that decision the provisions are not deemed to have been or to be so incorporated before the application for exemption or modification has been disposed of finally²⁷.

1 For the meaning of 'the ministers' see PARA 3 note 3 ante.

2 As to the making of regulations see PARA 5 ante.

3 I.e. for the purposes of the Medicines Act 1968 Pt II (ss 6-50) (as amended).

4 Ibid s 47(1). For the meaning of 'medicinal product' see PARA 7 ante. Standard provisions have been prescribed for product licences, manufacturer's licences and wholesale dealer's licences: see the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971, SI 1971/972 (amended by SI 1972/1226; SI 1974/1523; SI 1977/675; SI 1977/1039; SI 1977/1053; SI 1983/1730; SI 1992/2846; SI 1992/3272; SI 1993/833; SI 1993/2539; SI 1994/103; SI 1999/4; SI 2002/236; SI 2003/2321; SI 2003/3309; SI 2004/1031; SI 2004/1678; SI 2005/50; SI 2005/1710). For the meaning of 'product licence' see PARA 44 note 5 ante; for the meaning of 'manufacturer's licence' see PARA 46 note 7 ante; and for the meaning of 'wholesale dealer's licence' see PARA 47 note 12 ante. Regulations have also been made in respect of manufacturer's licences for veterinary medicinal products: see the Medicines (Standard Provisions for Manufacturer's Licences for Veterinary Medicinal Products) Regulations 1994, SI 1994/2852 (amended by SI 1994/3142).

5 I.e. with or without modifications and either generally or in relation to medicinal products of any particular class: Medicines Act 1968 s 47(2). The powers conferred on the licensing authority to vary a licence (see PARA

70 post) or certificate (see PARA 132 post) are exercisable with respect to any provisions incorporated or deemed to be incorporated in accordance with s 47 (as amended): s 47(9).

6 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

7 As to the grant of licences see PARA 61 ante.

8 For the meaning of 'animal test certificate' see PARA 127 note 14 post.

9 Medicines Act 1968 s 47(2) (amended by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 54, Sch 10 Pt I para 15).

10 Medicines Act 1968 s 47(3)(a).

11 Ibid s 47(3)(b).

12 For the meaning of 'month' see PARA 22 note 15 ante.

13 The 'relevant regulations' means the regulations prescribing the conditions or, as the case may be, the subsequent regulations amending or superseding the original regulations: Medicines Act 1968 s 47(3).

14 The 'operative standard provisions' means the standard provisions prescribed by the regulations or, as the case may be, the standard provisions as amended or superseded by the subsequent regulations: ibid s 47(3).

15 The operative standard provisions are not by virtue of ibid s 47(4) (as amended) to be incorporated in any licence of right (see PARA 12 note 23 ante) or in any certificate issued under s 37(4) (repealed), including any such licence or certificate which has been renewed, except in circumstances where immediately before 1 September 1971 the manufacture or importation of substances or articles to which the licence or certificate relates was authorised by a licence issued under the Therapeutic Substances Act 1956 Pt I (ss 1-7) (repealed) or under the Diseases of Animals Act 1950 Pt II (ss 52-56) (repealed): Medicines Act 1968 s 47(5). Where these circumstances exist, the provisions are deemed to be incorporated only in relation to substances or articles to which the licence so issued was applicable: s 47(5). As to the meaning of 'manufacture' see PARA 7 note 2 ante. For the meaning of 'import' see PARA 7 note 3 ante. For the meaning of 'substance' see PARA 7 note 1 ante.

16 Ibid s 47(4) (amended by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, Sch 10 Pt I para 15).

17 As to references to the holder of a licence or certificate see PARA 66 note 5 ante.

18 Such a direction has effect notwithstanding the Medicines Act 1968 s 47(4) (as amended) (see the text to notes 12-16 supra): s 47(6). As to the principles governing the exercise by public bodies of their statutory powers see ADMINISTRATIVE LAW vol 1(1) (2001 Reissue) PARA 16 et seq.

19 Ibid s 47(6)(a).

20 Ibid s 47(6)(b).

21 For the meaning of 'written' see PARA 21 note 4 ante.

22 Medicines Act 1968 s 47(7). As to the procedure to be followed by a person appointed see the Medicines Act 1968 (Hearings by Persons Appointed) Rules 1986, SI 1986/1761.

23 As to the service of notices see PARA 37 note 8 ante.

24 Medicines Act 1968 s 47(7).

25 Ibid s 47(8)(a).

26 Ie under ibid s 107: see PARA 79 post.

27 Ibid s 47(8)(b). So much of s 27(7) as relates to the time when an application is to be taken to be finally disposed of has effect also for these purposes: 47(8). An application is to be taken to be finally disposed of on, but not before, the occurrence of whichever of the following events last occurs, that is to say: (1) the licensing authority makes a decision determining the application (s 27(7)(a)); (2) the time within which an application under s 107 (see PARA 79 post) with respect to that decision can be made expires without its having been made (s 27(7)(b)); (3) if such an application under s 107 is made, the proceedings on the application under that provision are finally determined or abandoned or otherwise disposed of (s 27(7)(c)); (4) if there is an appeal

against the decision in any such proceedings as are mentioned in head (3) supra, or an appeal against the decision on such an appeal, the proceedings on that appeal are finally determined or abandoned or otherwise disposed of (s 27(7)(d)); (5) the time for bringing any such appeal as is mentioned in head (4) supra expires without its having been brought (s 27(7)(e)).

UPDATE

67 Standard provisions for licences or certificates

NOTE 4--SI 1971/972 replaced, in relation to manufacturer's licences and wholesale dealer's licences in so far as such licences relate to relevant medicinal products, by the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005, SI 2005/2789 (amended by SI 2009/1164). For these purposes 'relevant medicinal product' means a medicinal product for human use to which the provisions of the Directive apply; the 'Directive' means European Parliament and EC Council Directive 2001/83 on the Community code relating to medicinal products for human use: SI 2005/2789 reg 1. SI 1971/972 further amended, SI 1994/2852 revoked: SI 2005/2745.

NOTE 22--SI 1986/1761 amended: SI 2005/2745, SI 2008/2683.

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68. Renewal of licences.

Any licence¹, if it has not been revoked², may be renewed by the licensing authority³, on the application of the holder⁴, for a further period of five years⁵ from the date on which it would otherwise expire or the date from which it was last renewed, as the case may be, or such shorter period from that date as the authority may determine⁶. On an application for renewal⁷ the authority may renew the licence, with or without modifications, for such further period as is mentioned above⁸; or may grant a new licence containing such provisions as the authority considers appropriate⁹; or may refuse to renew the licence or to grant a new licence if, having regard to the provisions of the Medicines Act 1968 and any Community obligation¹⁰, it considers it necessary or expedient to do so¹¹.

Certain procedural and other provisions as to the grant or refusal of a licence¹² apply to renewals¹³.

1 le any licence granted under the Medicines Act 1968 Pt II (ss 6-50) (as amended).

2 As to the revocation of licences see PARA 70 post.

3 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

4 As to references to the holder of a licence see PARA 66 note 5 ante.

5 As to the duration of licences see PARA 69 post.

6 Medicines Act 1968 s 24(2) (amended by the Medicines (Medicines Act 1968 Amendment) Regulations 1977, SI 1977/1050, reg 4(4)).

7 Every application for the grant or renewal of a licence must, unless it otherwise expressly provides, be taken to be an application for the grant or renewal for the full five-year period: Medicines Act 1968 s 24(5). Any reference in Pt II (as amended) (including a reference implied by virtue of s 24(4) (see note 13 infra)) to the grant or renewal of a licence otherwise than in accordance with the application must be construed accordingly: s 24(5). Regulations provide the form and manner in which applications for the renewal of licences are to be made, and specify the particulars, information and samples that must be contained in or must accompany an application: see the Medicines (Renewal Applications for Licences and Certificates) Regulations 1974, SI 1974/832 (amended by SI 1977/180; SI 1982/1789; SI 1992/755; SI 1993/1227; SI 2004/1031). In respect of applications relating to veterinary medicinal products see the Medicines (Veterinary Drugs) (Renewal Applications for Licences and Animal Test Certificates) Regulations 1994, SI 1994/3143 (amended by SI 1996/2194); and the Medicines (Veterinary Medicinal Products) (Renewal Applications for Product Licences Subject to Review) Regulations 1993, SI 1993/2399, which relate to applications where the authority has served a notice under the Medicines Act 1968 s 24(1A) (as added) (see PARA 69 post). As to fees on applications see the Medicines (Products for Human Use--Fees) Regulations 1995, SI 1995/1116 (amended by SI 1996/683; SI 1998/574; SI 1999/566; SI 2000/592; SI 2000/3031; SI 2001/795; SI 2002/236; SI 2002/542; SI 2003/625; SI 2003/2321; SI 2004/666; SI 2004/1157; SI 2005/1124); and the Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750 (amended by SI 2004/3081). Where an application for renewal has been duly made, the licence does not cease to be in force before the authority has determined the application (Medicines Act 1968 s 24(6)(a)); and if, by an interim order under s 107(3)(a) (see PARA 79 post), the operation of the decision on the application is suspended, the licence does not cease to be in force so long as the suspension continues (s 24(6)(b)).

8 Ibid s 24(3)(a).

9 Ibid s 24(3)(b).

10 le under EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) on the Community code relating to medicinal products for human use (as amended), other than Titles VI, VII and VIII. For the

meaning of 'Community obligation' see the European Communities Act 1972 s 1, Sch 1 Pt II; and the Interpretation Act 1978 s 5, Sch 1.

11 Medicines Act 1968 s 24(3)(c) (amended by the Medicines Act 1968 (Amendment) (No 2) Regulations, SI 1994/276, reg 5; and the Medicines (Codification Amendments Etc) Regulations 2002, SI 2002/236, reg 2(c)(ii)). As to questioning the validity of the authority's decisions see PARA 79 post.

12 Ie the provisions of the Medicines Act 1968 s 18 (as amended) (see PARA 56 ante), s 19 (see PARAS 58-60 ante), s 20(2)-(5) (as amended) (see PARAS 61, 65 ante), ss 21-22 (as substituted) and s 22A (as added) (see PARAS 62-64 ante).

13 Ibid s 24(4) (amended by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 8, Sch 1 para 4). The provisions mentioned in note 12 supra have effect as if any reference to refusing a licence included a reference to refusing to renew a licence and any reference to granting a licence included a reference to renewing it: see the Medicines Act 1968 s 24(4) (as so amended).

UPDATE

68 Renewal of licences

TEXT AND NOTES 1-6--The 1968 Act s 24(2) does not apply to a licence insofar as it relates to a medicinal product to which European Parliament and EC Council Directive 2001/83 on the Community code relating to medicinal products for human use applies: 1968 Act s 24(2A) (added by the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005, SI 2005/2789).

TEXT AND NOTES 7-11--References to a licence in the 1968 Act s 24(3) are to be read as references to a licence only insofar as that licence relates to a medicinal product to which European Parliament and EC Council Directive 2001/83 does not apply: 1968 Act s 24(3A) (added by SI 2005/2789).

NOTE 7--The 1968 Act s 24(5) does not apply to a licence insofar as it relates to a medicinal product to which European Parliament and EC Council Directive 2001/83 applies: 1968 Act s 24(5A) (added by SI 2005/2789). SI 1974/832 revoked, in relation to manufacturer's licences and wholesale dealer's licences in so far as such licences relate to relevant medicinal products, by SI 2005/2789. For these purposes 'relevant medicinal product' means a medicinal product for human use to which the provisions of the Directive apply; the 'Directive' means European Parliament and EC Council Directive 2001/83: SI 2005/2789 reg 1. SI 1993/2399, SI 2004/2750 revoked: SI 2005/2745. SI 1995/1116 replaced: see now the Medicines (Products for Human Use) (Fees) Regulations 2009, SI 2009/389 (SI 2009/3222).

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(vi) Duration, Suspension and Revocation of Licences

69. Duration of licences.

Unless previously renewed¹ or revoked², every licence³ expires at the end of the period of five years from the date on which it was granted or the date as from which it was last renewed, as the case may be, or at the end of such shorter period from that date as may be specified in the licence as granted or last renewed⁴. Where a licence has been granted and the licensing authority⁵ subsequently considers that it would no longer be possible to grant that licence without contravening a Community obligation⁶, the licence expires on a date specified in a notice served⁷ on the holder⁸ of the licence by the authority⁹.

1 As to the renewal of licences see PARA 68 ante.

2 As to the revocation of licences see PARA 70 post.

3 I.e. granted under the Medicines Act 1968 Pt II (ss 6-50) (as amended). As to the grant of licences see PARA 61 ante.

4 Ibid s 24(1).

5 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

6 I.e. other than an obligation under EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) on the Community code relating to medicinal products for human use, Title V: Medicines Act 1968 s 24(1A) (added by the Medicines (Medicines Act 1968 Amendment) Regulations 1977, SI 1977/1050, reg 4(4); and amended by the Medicines Act 1968 (Amendment) (No 2) Regulations, SI 1994/276, reg 5(a); and the Medicines (Codification Amendments Etc) Regulations 2002, SI 2002/236, reg 2(c)(i)). For the meaning of 'Community obligation' see the European Communities Act 1972 s 1, Sch 1 Pt II; and the Interpretation Act 1978 s 5, Sch 1.

7 As to the service of notices see PARA 37 note 8 ante.

8 As to references to the holder of a licence see PARA 66 note 5 ante.

9 Medicines Act 1968 s 24(1A) (as added: see note 6 supra).

UPDATE

69 Duration of licences

TEXT AND NOTES 1-4--Replaced. A licence granted under the 1968 Act Pt II (ss 6-50) expires in accordance with the provisions of the licence, or, if there is no such provision, at the end of the period of five years beginning with the date on which the licence was granted, or if it has been renewed the date on which it was last renewed: s 24(1) (substituted by the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005, SI 2005/2789). But so far as the licence relates to a medicinal product to which European Parliament and EC Council Directive 2001/83 applies, it remains in force until revoked by the licensing authority, or surrendered by the holder: 1968 Act s 24(1AA) (added by SI 2005/2789).

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70. Power to suspend, revoke or vary licences.

On certain grounds¹ the licensing authority² may suspend a licence³ for such period as it may determine, or may revoke or vary the provisions of any such licence⁴. The suspension or revocation may be total or may be limited to medicinal products⁵ of one or more descriptions⁶ or to medicinal products manufactured⁷, assembled⁸ or stored on any particular premises or in a particular part of any premises⁹.

Where it appears to the authority, or where it is represented to it by the appropriate committee¹⁰, that circumstances exist by reason of which it is necessary to consider whether the licence should be varied, suspended or revoked¹¹, the authority may serve¹² on the holder¹³ of a licence a notice requiring him, within a specified time, to furnish to it information of any description specified in the notice¹⁴, being information such as appears to it, or is represented to it by the committee, to be requisite for considering the question¹⁵.

1 In relation to product licences see PARA 71 post; and in relation to manufacturer's and wholesale dealer's licences see PARA 72 post.

2 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

3 I.e. a licence granted under the Medicines Act 1968 Pt II (ss 6-50) (as amended). As to the grant of licences see PARA 61 ante.

4 Ibid s 28(1). As to the duty of the authority to serve on the licence holder notice of its decision see PARA 77 post. As to challenging the authority's decision see s 107; and PARA 79 post.

5 For the meaning of 'medicinal product' see PARA 7 ante.

6 As to the description of medicinal products see PARA 7 note 33 ante.

7 As to the meaning of 'manufacture' see PARA 7 note 2 ante.

8 For the meaning of 'assemble' see PARA 6 note 8 ante.

9 Medicines Act 1968 s 28(2).

10 For the meaning of 'the appropriate committee' see PARA 15 note 5 ante.

11 Medicines Act 1968 s 44(3) (amended by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 8, Sch 1 para 9).

12 As to the service of notices see PARA 37 note 8 ante.

13 As to references to the holder of a licence see PARA 66 note 5 ante.

14 Medicines Act 1968 s 44(2) (amended by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 54, Sch 10 Pt I para 12). This provision applies also to animal test certificates (see PARA 132 post): Medicines Act 1968 s 44(2) (as so amended). Except in the case of a licence of right under s 25 (see PARA 12 note 23 ante) or a transitional clinical trial or animal test certificate under s 37(4) (repealed), the authority may not serve such a notice except in the circumstances set out in the text to notes 10-11 supra: see s 44(3), (4) (s 44(3) as amended: see note 11 supra). In the case of any such licence or certificate, whether or not it has been renewed, the authority's powers are not so restricted: a notice may be served at any time and may require any information which in the authority's opinion would be relevant if s 25 and s 37(4) (repealed) had not been enacted and the authority was then dealing with an application by the present holder for the grant or issue of a licence or certificate containing the same provisions as those contained in the licence or certificate in question: see s 44(4).

15 Ibid s 44(3) (as amended: see note 11 supra).

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71. Grounds for suspension of product licences.

The powers¹ of the licensing authority² to suspend, revoke or vary licences are not exercisable by the authority in relation to a product licence³ except on one or more of the following grounds⁴:

- 70 (1) that the matters stated in the application⁵ on which the licence was granted were false or incomplete in a material particular⁶;
- 71 (2) that any provision of the licence has to a material extent been contravened by the holder of the licence or by a person procured by him to manufacture or assemble medicinal products⁷ of a description⁸ to which the licence relates⁹;
- 72 (3) that medicinal products of any such description, as sold, supplied, exported¹⁰, imported¹¹, manufactured or assembled in pursuance of the licence, fail to a material extent to correspond to the characteristics by reference to which the licence was granted¹²;
- 73 (4) that the holder has failed without reasonable excuse to comply with a requirement¹³ to furnish information with respect to medicinal products of any such description¹⁴;
- 74 (5) that any premises on which, or in part of which, medicinal products of any such description are manufactured, assembled or stored by or on behalf of the holder are unsuitable¹⁵;
- 75 (6) in the case of a licence other than a licence of right¹⁶, that the holder has not, within two years after the grant of the licence, notified to the licensing authority, in relation to each description of medicinal products to which the licence relates, a date on which products of that description were effectively on the market in the United Kingdom¹⁷;
- 76 (7) that medicinal products of any description to which the licence relates can no longer be regarded as products which can safely¹⁸ be administered¹⁹ for the purposes indicated in the licence, or can no longer be regarded as efficacious for those purposes²⁰;
- 77 (8) that the specification and standards to which medicinal products of any such description are manufactured can no longer be regarded as satisfactory²¹;
- 78 (9) that any of the provisions of the licence, in so far as they relate to the incorporation in animal feeding stuffs²² of any medicinal product are not in accordance with any Community obligation²³; and
- 79 (10) that, in relation to medicinal products of any description to which the licence relates²⁴, any of the provisions contained in regulations²⁵ relating to the labelling²⁶ and marking of containers and packages²⁷ imposing requirements which give effect to Community obligations²⁸ has to a material extent been contravened by the holder of the licence or by a person procured by him to manufacture or assemble such medicinal products²⁹.

1 le the powers conferred by the Medicines Act 1968 s 28(1): see PARA 70 ante.

2 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

3 For the meaning of 'product licence' see PARA 44 note 5 ante.

4 Medicines Act 1968 s 28(3) (amended by the Medicines Act 1968 (Amendment) (No 2) Regulations, SI 1994/276, reg 6(2)(a)). The provisions of the Medicines Act 1968 s 28 (as amended) are subject to those of s 29 (see PARA 73 et seq post): s 28(7). Where a product licence relates to a product to which EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) on the Community code relating to medicinal products for human use (as amended) applies, the power conferred by the Medicines Act 1968 s 28 (as amended) to suspend a licence is exercisable in relation to the licence on the ground that any of the provisions contained in regulations made under s 85 (labelling and marking of containers and packages: see PARA 152 post) or s 86 (as amended) (leaflets: see PARA 153 post), or s 86(4) (as added and amended) (see PARA 153 post), has to a material extent been contravened in relation to the product by the holder of the licence or by a person procured by him to manufacture or assemble the product: s 28(3A) (added by the Medicines Act 1968 (Amendment) (No 2) Regulations, SI 1994/276, reg 6(3); and amended by the Medicines (Codification Amendments Etc) Regulations 2002, SI 2002/236, reg 2(a)(iii)). As to references to the holder of a licence see PARA 66 note 5 ante. As to the meaning of 'manufacture' see PARA 7 note 2 ante. For the meaning of 'assemble' see PARA 6 note 8 ante.

5 As to applications see PARA 56 ante. For the power to require further information in relation to applications see PARA 57 ante.

6 Medicines Act 1968 s 28(3)(a). As to the requirement for the authority to consult with the appropriate committee in relation to this ground see PARA 73 post.

7 For the meaning of 'medicinal product' see PARA 7 ante.

8 As to the description of medicinal products see PARA 7 note 33 ante.

9 Medicines Act 1968 s 28(3)(b).

10 For the meaning of 'export' see PARA 7 note 4 ante.

11 For the meaning of 'import' see PARA 7 note 3 ante.

12 Medicines Act 1968 s 28(3)(c). As to the requirement for the authority to consult with the appropriate committee in relation to this ground see PARA 73 post.

13 I.e. a requirement imposed on him under *ibid* s 44(2) (as amended): see PARA 70 ante.

14 *Ibid* s 28(3)(d).

15 *Ibid* s 28(3)(e).

16 As to licences of right see PARA 12 note 23 ante.

17 Medicines Act 1968 s 28(3)(f). For the obligation to notify the authority when products covered by a licence are effectively on the United Kingdom market see s 44(5); and PARA 80 post. As to the meaning of 'effectively on the market in the United Kingdom' see PARA 44 note 18 ante. For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

18 As to considerations of safety see PARA 15 note 10 ante.

19 As to the meaning of 'administer' see PARA 7 note 2 ante.

20 Medicines Act 1968 s 28(3)(g). As to the requirement for the authority to consult with the appropriate committee in relation to this ground see PARA 73 post. Factors which were relevant to the granting of a product licence are also relevant to the consideration of the suspension, variation or revocation of a licence on this ground: *Organon Laboratories Ltd v Department of Health and Social Security* [1990] 2 CMLR 491, CA.

21 Medicines Act 1968 s 28(3)(h). As to the requirement for the authority to consult with the appropriate committee in relation to this ground see PARA 73 post.

22 For the meaning of 'animal feeding stuffs' see PARA 7 note 2 ante.

23 Medicines Act 1968 s 28(3)(i) (added by the Medicines (Medicines Act 1968 Amendment) Regulations 1975, SI 1975/1169, reg 2; and amended by the Animal Health and Welfare Act 1984 s 16, Sch 1 para 3 (2)). For the meaning of 'Community obligation' see the European Communities Act 1972 s 1, Sch 1 Pt II; and the Interpretation Act 1978 s 5, Sch 1.

24 I.e. other than products to which EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) on the Community code relating to medicinal products for human use (as amended) applies: Medicines Act

1968 s 28(3)(j) (added by the Medicines (Medicines Act 1968 Amendment) Regulations 1977, SI 1977/1050, reg 4 (1), (5); and amended by the Medicines Act 1968 (Amendment) (No 2) Regulations, SI 1994/276, reg 6(2)(b); and the Medicines (Codification Amendments Etc) Regulations 2002, SI 2002/236, reg 2(a)(iii)).

25 le made under the Medicines Act 1968 s 85: see PARA 152 post.

26 For the meaning of 'labelling' see PARA 152 note 4 post.

27 Medicines Act 1968 s 28(3)(j)(i) (as added and amended: see note 24 supra). For the meanings of 'container' and 'package' see PARA 152 note 4 post.

28 Ibid s 28(3)(j)(ii) (as added and amended: see note 24 supra).

29 Ibid s 28(3)(j) (as added and amended: see note 24 supra).

UPDATE

71 Grounds for suspension of product licences

NOTES--Certain functions under provisions mentioned in this paragraph are 'relevant functions' for the purposes of the Regulatory Enforcement and Sanctions Act 2008 s 4, Sch 3, see LOCAL GOVERNMENT vol 69 (2009) PARA 733.

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72. Grounds for suspension of manufacturer's and wholesale dealer's licences.

The powers¹ of the licensing authority² to suspend, revoke or vary licences are not exercisable in relation to a manufacturer's licence³ or a wholesale dealer's licence⁴ except on one or more of the following grounds: (1) that the matters stated in the application⁵ on which the licence was granted were false or incomplete in a material particular⁶; (2) that a material change of circumstances has occurred in relation to any of those matters⁷; (3) that any of the provisions of the licence has to a material extent been contravened by the holder of the licence⁸; (4) that the holder has without reasonable excuse failed to comply with a requirement⁹ to furnish information with respect to medicinal products¹⁰ of a description¹¹ to which the licence relates¹².

In relation to a manufacturer's licence, the powers are exercisable on either of the following grounds in addition to those specified above: (a) that the holder has carried out processes of manufacture¹³ or assembly¹⁴ to the order of another person¹⁵ who is the holder of a product licence¹⁶, and has habitually failed to comply with the provisions of that product licence¹⁷; (b) that the holder of the manufacturer's licence does not have the requisite facilities for properly carrying out processes of manufacture or assembly authorised by the licence¹⁸.

In relation to a wholesale dealer's licence, the powers are exercisable on the following additional ground: that the equipment and facilities for storing or distributing medicinal products which are available to the holder of the licence are inadequate to maintain the quality of medicinal products of one or more descriptions to which the application for the licence related¹⁹.

1 Ie the powers conferred by the Medicines Act 1968 s 28(1): see PARA 70 ante.

2 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

3 For the meaning of 'manufacturer's licence' see PARA 46 note 7 ante.

4 For the meaning of 'wholesale dealer's licence' see PARA 47 note 12 ante.

5 As to applications see PARA 56 ante. For the power to require further information in relation to applications see PARA 57 ante.

6 Medicines Act 1968 s 28(4)(a). The provisions of s 28 (as amended) are subject to those of s 29 (see PARA 73-77 post): s 28(7).

7 Ibid s 28(4)(b).

8 Ibid s 28(4)(c). As to references to the holder of a licence see PARA 66 note 5 ante.

9 Ie a requirement imposed on him under ibid s 44(2) (as amended): see PARA 70 ante.

10 For the meaning of 'medicinal product' see PARA 7 ante.

11 As to the description of medicinal products see PARA 7 note 33 ante.

12 Medicines Act 1968 s 28(4)(d).

13 As to the meaning of 'manufacture' see PARA 7 note 2 ante.

14 For the meaning of 'assembly' see PARA 6 note 8 ante.

- 15 For the meaning of 'person' see PARA 21 note 7 ante.
- 16 For the meaning of 'product licence' see PARA 44 note 5 ante.
- 17 Medicines Act 1968 s 28(5)(a).
- 18 Ibid s 28(5)(b).
- 19 Ibid s 28(6).

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73. Consultation with appropriate committee.

Except in cases of urgency¹, where the licensing authority² proposes, in the exercise of its powers to suspend, revoke or vary licences³, to:

- 80 (1) suspend, revoke or vary a product licence⁴ on grounds relating to the content of the application⁵ or the failure of the medicinal products⁶ to correspond to the characteristics by reference to which the licence was granted⁷, in a case where it appears to the licensing authority that the matters or characteristics in question are such as to affect the safety⁸, efficacy or quality of medicinal products to which the licence relates⁹; or
- 81 (2) suspend, revoke or vary a product licence on the grounds that medicinal products can no longer be regarded as safe or efficacious¹⁰ or that the specification and standards to which medicinal products are manufactured can no longer be regarded as satisfactory¹¹,

the licensing authority must not suspend, revoke or vary the licence except after consultation with the appropriate committee¹².

Where the appropriate committee is consulted and is of the provisional opinion that, on such grounds as are mentioned above, it may have to advise the licensing authority that the product licence ought to be revoked, varied or suspended, the committee must notify¹³ the holder of the licence¹⁴ accordingly¹⁵. A person¹⁶ who has been so notified may, within the time allowed¹⁷, give notice of his wish to make written¹⁸ or oral representations to the committee¹⁹ and the committee must give the holder of the licence an opportunity to make such representations²⁰. The committee must take into account such representations as are made²¹ and report its findings and advice to the licensing authority, together with the reasons for that advice²².

After receiving the committee's report, the licensing authority must decide whether to continue with the proposal to revoke, vary or suspend the product licence²³, and must take the report into account when making its decision²⁴. The licensing authority must then notify the holder of the licence of its decision²⁵ and the advice given to it by the committee, and the reasons for that advice²⁶. A person to whom such a notification has been given may, within the time allowed, notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority with respect to the decision²⁷.

If the appropriate committee was consulted²⁸, the committee did not give a provisional opinion²⁹ and the licensing authority proposes to determine the matter in a way which differs from the advice of the committee³⁰, or to suspend, revoke or vary the licence on grounds not relating to safety, quality or efficacy³¹, the authority must notify the holder of the licence accordingly³². A person to whom such a notification has been given may, within the time allowed, notify the licensing authority that he wishes to appear before and be heard by a person appointed for the purpose by the licensing authority³³, or make representations in writing to the licensing authority with respect to the proposal referred to in the notification³⁴. If the applicant makes written representations, the licensing authority must take those representations into account before determining the matter³⁵.

1 As to cases of urgency see PARA 76 post.

- 2 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.
- 3 le under the Medicines Act 1968 s 28 (as amended): see PARA 70 ante.
- 4 For the meaning of 'product licence' see PARA 44 note 5 ante.
- 5 le the grounds specified in the Medicines Act 1968 s 28(3)(a): see PARA 71 head (1) ante.
- 6 For the meaning of 'medicinal product' see PARA 7 ante.
- 7 le the grounds specified in the Medicines Act 1968 s 28(3)(c): see PARA 71 head (3) ante.
- 8 As to considerations of safety see PARA 15 note 10 ante.
- 9 Medicines Act 1968 s 29(1), Sch 2 para 1(a) (Sch 2 substituted by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 8, Sch 1 para 15).
- 10 le the grounds specified in the Medicines Act 1968 s 28(3)(g): see PARA 71 head (7) ante.
- 11 Ibid Sch 2 para 1(b) (as substituted: see note 9 supra). The grounds referred to in the text are those specified in s 28(3)(h): see PARA 71 head (8) ante.
- 12 Ibid Sch 2 para 1 (as substituted: see note 9 supra). For the meaning of 'the appropriate committee' see PARA 15 note 5 ante.
- 13 As to the service of notices see PARA 37 note 8 ante.
- 14 As to references to the holder of a licence see PARA 66 note 5 ante.
- 15 Medicines Act 1968 Sch 2 para 2(1) (as substituted: see note 9 supra).
- 16 For the meaning of 'person' see PARA 21 note 7 ante.
- 17 'The time allowed' means the period of 28 days from the date of the relevant notification, or such longer period as the licensing authority may allow in any particular case: Medicines Act 1968 Sch 2 para 12 (as substituted: see note 9 supra).
- 18 For the meaning of 'written' see PARA 21 note 4 ante.
- 19 Medicines Act 1968 Sch 2 para 2(2) (as substituted: see note 9 supra).
- 20 Ibid Sch 2 para 2(3) (as substituted: see note 9 supra). The holder of the licence must provide the committee with:
 - 57 (1) his written representations or a written summary of the oral representations he intends to make (Sch 2 para 2(4)(a) (as so substituted)); and
 - 58 (2) any documents on which he wishes to rely in support of those representations (Sch 2 para 2(4)(b) (as so substituted)),before the end of the period of six months beginning with the date of his notice, or within such shorter period as the committee may specify in the notification (Sch 2 para 2(4) (as so substituted)). For the meaning of 'month' see PARA 22 note 15 ante. If the holder of the licence so requests, the committee may extend the time limit up to a maximum period of 12 months beginning with the date of the holder's notice: Sch 2 para 2(5) (as so substituted). The holder of the licence may not submit any additional written representations or documents once the time limit has expired, except with the permission of the committee: Sch 2 para 2(6) (as so substituted). If the holder gave notice of his wish to make oral representations, the committee must, after receiving a written summary and any other documents from him, arrange for the holder to make such representations at a hearing before the committee: Sch 2 para 2(7) (as so substituted).
- 21 Ibid Sch 2 para 2(8)(a) (as substituted: see note 9 supra).
- 22 Ibid Sch 2 para 2(8)(b) (as substituted: see note 9 supra).
- 23 Ibid Sch 2 para 3(1)(a) (as substituted: see note 9 supra).
- 24 Ibid Sch 2 para 3(1)(b) (as substituted: see note 9 supra).

25 Ibid Sch 2 para 3(2)(a) (as substituted: see note 9 supra). As to the duty of the authority to serve on the licence holder notice of its decision see PARA 77 post.

26 Ibid Sch 2 para 3(2)(b) (as substituted: see note 9 supra).

27 Ibid Sch 2 para 5(1) (as substituted: see note 9 supra). This provision does not apply where: (1) the person has not made any representations in accordance with Sch 2 para 2(4)-(7) (as substituted) (see note 20 supra) (Sch 2 para 5(4)(a) (as so substituted)); and (2) the decision of the licensing authority was in accordance with the advice of the committee (Sch 2 para 5(4)(b) (as so substituted)). As to the hearing before the person appointed see PARA 75 post.

28 Ibid Sch 2 para 4(1)(a) (as substituted: see note 9 supra).

29 Ibid Sch 2 para 4(1)(b) (as substituted: see note 9 supra).

30 Ibid Sch 2 para 4(1)(c)(i) (as substituted: see note 9 supra).

31 Ibid Sch 2 para 4(1)(c)(ii) (as substituted: see note 9 supra).

32 Ibid Sch 2 para 4(1) (as substituted: see note 9 supra). A notification must state: (1) the advice of the committee and the reasons stated by the committee for that advice (Sch 2 para 4(2)(a) (as so substituted)); and (2) the proposals of the licensing authority and the reasons for them (Sch 2 para 4(2)(b) (as so substituted)).

33 Ibid Sch 2 para 5(2)(a) (as substituted: see note 9 supra). As to the hearing before the person appointed see PARA 75 post.

34 Ibid Sch 2 para 5(2)(b) (as substituted: see note 9 supra).

35 Ibid Sch 2 para 5(3) (as substituted: see note 9 supra).

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74. Notification of proposals to holder of licence in other cases.

Except in cases of urgency¹, where the licensing authority² proposes, in the exercise of its powers³:

- 82 (1) to suspend, revoke or vary a licence⁴, other than a product licence⁵; or
- 83 (2) to suspend, revoke or vary a product licence where the holder of the licence⁶ has been given neither notice of any provisional opinion or any advice of the appropriate committee⁷ which led to that proposal⁸, nor notice⁹ of that proposal¹⁰,

the following procedure applies¹¹.

The licensing authority must notify¹² the holder of the licence of its proposals¹³, the reasons for them¹⁴ and the date on which it is proposed that the suspension, revocation or variation should take effect¹⁵. The holder of the licence may, before the date specified in the notification, notify the licensing authority of his wish to appear before and be heard by a person appointed by the authority with respect to the decision¹⁶, or make representations in writing¹⁷ to the licensing authority with respect to the proposal referred to in the notification¹⁸. If the applicant makes written representations, the licensing authority must take those representations into account before determining the matter¹⁹.

1 As to cases of urgency see PARA 76 post.

2 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

3 I.e. the powers conferred by the Medicines Act 1968 s 28 (as amended): see PARA 70 ante.

4 I.e. a licence under ibid Pt 2 (ss 6-50) (as amended). As to such licences see PARAS 44-47 ante. As to applications for licences see PARA 56 ante.

5 Ibid s 29(1), Sch 2 para 6(1)(a) (Sch 2 substituted by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 8, Sch 1 para 15). For the meaning of 'product licence' see PARA 44 note 5 ante.

6 As to references to the holder of a licence see PARA 66 note 5 ante.

7 I.e. under the Medicines Act 1968 Sch 2 paras 2, 3 (as substituted): see PARA 73 ante. For the meaning of 'the appropriate committee' see PARA 15 note 5 ante.

8 Ibid Sch 2 para 6(1)(b)(i) (as substituted: see note 5 supra).

9 I.e. under ibid Sch 2 para 4 (as substituted): see PARA 73 ante.

10 Ibid Sch 2 para 6(1)(b)(ii) (as substituted: see note 5 supra).

11 Ibid Sch 2 para 6(1) (as substituted: see note 5 supra).

12 As to the service of notices see PARA 37 note 8 ante.

13 Medicines Act 1968 Sch 2 para 6(2)(a) (as substituted: see note 5 supra).

14 Ibid Sch 2 para 6(2)(b) (as substituted: see note 5 supra).

15 Ibid Sch 2 para 6(2)(c) (as substituted: see note 5 supra). The date must not be earlier than 28 days from the date of the notification: Sch 2 para 6(2)(c) (as so substituted).

16 Ibid Sch 2 para 6(3)(a) (as substituted: see note 5 supra). As to hearings before a person appointed see PARA 75 post.

17 For the meaning of 'writing' see PARA 21 note 6 ante.

18 Medicines Act 1968 Sch 2 para 6(3)(b) (as substituted: see note 5 supra).

19 Ibid Sch 2 para 6(4) (as substituted: see note 5 supra). As to the duty of the authority to serve on the licence holder notice of its decision see PARA 77 post.

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75. Hearing before person appointed.

If the holder of the licence¹ gives notice² of his wish to appear before and be heard by a person appointed by the licensing authority³, the authority must make an appointment⁴ and arrange for the applicant to have an opportunity of appearing before that person⁵. The holder of the licence must, before the end of the period of three months⁶ beginning with the date of his notice, provide the person appointed with a written⁷ summary of the oral representations he intends to make⁸ and any documents on which he wishes to rely in support of those representations⁹. If the holder of the licence fails to comply with the time limit, or any extension, he may not appear before or be heard by the person appointed¹⁰; and the licensing authority must decide whether to grant or refuse the licence, or to grant it otherwise than in accordance with the application, and notify¹¹ the applicant accordingly¹².

At the hearing before the person appointed, both the holder of the licence and the licensing authority may make representations¹³. If the holder of the licence so requests, the hearing must be in public¹⁴. After the hearing the person appointed must provide a report to the licensing authority¹⁵ which must take this report into account and decide whether to revoke, vary or suspend the licence¹⁶. The licensing authority must then notify the holder of the licence of its decision¹⁷ and, if the holder so requests, provide the holder with a copy of the report of the person appointed¹⁸.

1 As to references to the holder of a licence see PARA 66 note 5 ante. As to licences see PARAS 44-47 ante. As to applications for licences see PARA 56 ante.

2 See under the Medicines Act 1968 s 29(1), Sch 2 paras 5, 6 (as substituted): see PARAS 73-74 ante.

3 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

4 Medicines Act 1968 Sch 2 para 7(1)(a) (Sch 2 substituted by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 8, Sch 1 para 15). The person appointed must not be, or at any time have been, a member of the Commission on Human Medicines or any of its expert advisory groups (Medicines Act 1968 Sch 2 para 7(2)(a)(i) (as so substituted)), the Medicines Commission formerly established under s 2 (repealed) or any of its committees (Sch 2 para 7(2)(a)(ii) (as so substituted)), or a committee established under s 4 (as amended) or any sub-committee of such a committee (Sch 2 para 7(2)(a)(iii) (as so substituted)); and must not be an officer or servant of any Minister of the Crown (Sch 2 para 7(2)(b) (as so substituted)). As to the Commission on Human Medicines, expert advisory groups and committees see PARAS 13-17 ante. As to the former Medicines Commission see PARA 13 note 1 ante. As to Ministers of the Crown see CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARA 354 et seq.

5 Ibid Sch 2 para 7(1)(b) (as substituted: see note 4 supra).

6 If the holder of the licence so requests, the person appointed may, after consulting the licensing authority, extend the time limit up to a maximum period of six months beginning with the date of the holder's notice: ibid Sch 2 para 7(4) (as substituted: see note 4 supra). For the meaning of 'month' see PARA 22 note 15 ante. The holder of the licence may not submit any additional written representations or documents once the time limit has expired, except with the permission of the person appointed: Sch 2 para 7(6) (as so substituted).

7 For the meaning of 'written' see PARA 21 note 4 ante.

8 Medicines Act 1968 Sch 2 para 7(3)(a) (as substituted: see note 4 supra).

9 Ibid Sch 2 para 7(3)(b) (as substituted: see note 4 supra).

10 Ibid Sch 2 para 7(5)(a) (as substituted: see note 4 supra).

11 As to the service of notices see PARA 37 note 8 ante.

12 Medicines Act 1968 Sch 2 para 7(5)(b) (as substituted: see note 4 supra). It is submitted that although the statute refers to the grant or refusal of the licence, or to the grant thereof otherwise than in accordance with the application, it should be taken to refer to the suspension, revocation or variation of the licence. As to the duty of the authority to serve on the licence holder notice of its decision see PARA 77 post. As to challenges to decisions of the licensing authority see s 107; and PARA 79 post. As to the principles governing the exercise by public bodies of their statutory powers and judicial control thereof see ADMINISTRATIVE LAW vol 1(1) (2001 Reissue) PARAS 16 et seq; JUDICIAL REVIEW.

13 Ibid Sch 2 para 7(7) (as substituted: see note 4 supra). For further provisions relating to the procedure at hearings see the Medicines Act 1968 (Hearings by Persons Appointed) Rules 1986, SI 1986/1761; and PARA 64 ante.

14 Medicines Act 1968 Sch 2 para 7(8) (as substituted: see note 4 supra).

15 Ibid Sch 2 para 7(9)(a) (as substituted: see note 4 supra).

16 Ibid Sch 2 para 7(9)(b) (as substituted: see note 4 supra).

17 Ibid Sch 2 para 7(10)(a) (as substituted: see note 4 supra).

18 Ibid Sch 2 para 7(10)(b) (as substituted: see note 4 supra).

UPDATE

75 Hearing before person appointed

NOTE 13--SI 1986/1761 amended: SI 2005/2745, SI 2008/2683.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(4) LICENCES AND LICENSING/(vi) Duration, Suspension and Revocation of Licences/76. Procedure in cases of urgency.

76. Procedure in cases of urgency.

Where it appears to the licensing authority¹ that in the interests of safety² it is necessary to suspend a licence³ with immediate effect, the licensing authority may do so for a period not exceeding three months⁴. If the licence is a product licence⁵, the licensing authority must report the suspension forthwith to the appropriate committee⁶.

If, after the suspension has taken effect, it appears to the licensing authority⁷ or, in the case of a product licence, the authority is advised by the appropriate committee⁸, that it is necessary to consider whether the licence ought to be further suspended, or ought to be revoked or varied, the licensing authority must proceed in accordance with such of the appropriate provisions⁹ as are applicable in the circumstances¹⁰. However, if any such proceedings relating to a further suspension of the licence have not been finally disposed of¹¹ before the end of the period for which the licence was originally¹² suspended¹³, or for which it has been further suspended¹⁴, the licensing authority may, if it appears to it to be necessary in the interests of safety to do so, further suspend the licence for a period which, in the case of each such further suspension, must not exceed three months¹⁵.

1 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

2 As to considerations of safety see PARA 15 note 10 ante.

3 I.e. a licence under the Medicines Act 1968 Pt II (ss 6-50) (as amended). As to such licences see PARAS 44-47 ante. As to applications for licences see PARA 56 ante.

4 Ibid s 29(1), Sch 2 para 8 (Sch 2 substituted by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 8, Sch 1 para 15). This is notwithstanding anything in the Medicines Act 1968 Sch 2 paras 1-7 (as substituted) (see PARAS 73-75 ante); Sch 2 para 8 (as so substituted). For the meaning of 'month' see PARA 22 note 15 ante. As to the duty of the authority to serve on the licence holder notice of its decision see PARA 77 post.

5 For the meaning of 'product licence' see PARA 44 note 5 ante.

6 Medicines Act 1968 Sch 2 para 9 (as substituted: see note 4 supra). For the meaning of 'the appropriate committee' see PARA 15 note 5 ante.

7 Ibid Sch 2 para 10(a) (as substituted: see note 4 supra).

8 Ibid Sch 2 para 10(b) (as substituted: see note 4 supra).

9 I.e. the provisions of ibid Sch 2 paras 1-7 (as substituted) (see PARAS 73-75 ante).

10 Ibid Sch 2 para 10 (as substituted: see note 4 supra).

11 The provisions of ibid s 27(7) (see PARA 67 note 27 ante) have effect, with the necessary modifications, for the purpose of determining the date on which any proceedings are taken to be finally disposed of: Sch 2 para 11(3) (as substituted: see note 4 supra).

12 I.e. under ibid Sch 2 para 8 (as substituted): see the text to notes 1-4 supra.

13 Ibid Sch 2 para 11(1)(a) (as substituted: see note 4 supra).

14 Ibid Sch 2 para 11(1)(b) (as substituted: see note 4 supra).

15 See ibid Sch 2 para 11(2) (as substituted: see note 4 supra).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(4) LICENCES AND LICENSING/(vi) Duration, Suspension and Revocation of Licences/77. Notice of particulars of and reasons for suspension etc.

77. Notice of particulars of and reasons for suspension etc.

Where the licensing authority¹ suspends, revokes or varies a licence², it must serve³ on the holder⁴ of the licence a notice giving particulars of the suspension, revocation or variation and of the reasons for its decision to suspend, revoke or vary the licence⁵.

1 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

2 I.e. a licence granted under the Medicines Act 1968 Pt II (ss 6-50) (as amended). As to the power to suspend, revoke or vary a licence, and as to the grounds and procedure for doing so, see PARAS 70-76 ante, 78 post.

3 As to the service of notices see PARA 37 note 8 ante.

4 As to references to the holder of a licence or certificate see PARA 66 note 5 ante.

5 Medicines Act 1968 s 29(2). This duty to serve a notice is without prejudice to any requirement of Sch 2 (as substituted) (see PARAS 73-76 ante) as to the service of notices: s 29(2).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(4) LICENCES AND LICENSING/(vi) Duration, Suspension and Revocation of Licences/78. Variation of licence on holder's application.

78. Variation of licence on holder's application.

On the application of the holder¹ of a licence², the licensing authority³ may vary the provisions of the licence in accordance with any proposals contained in the application, if it is satisfied that the variation will not adversely affect the safety⁴, quality or efficacy of medicinal products⁵ of any description⁶ to which the licence relates⁷.

1 As to references to the holder of a licence or certificate see PARA 66 note 5 ante.

2 I.e. a licence granted under the Medicines Act 1968 Pt II (ss 6-50) (as amended): see PARA 61 ante.

3 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

4 As to considerations of safety see PARA 15 note 10 ante.

5 For the meaning of 'medicinal product' see PARA 7 ante.

6 As to the description of medicinal products see PARA 7 note 33 ante.

7 Medicines Act 1968 s 30. This power to vary is expressed to be without prejudice to any power exercisable by virtue of s 28 (as amended) (see PARA 70 ante). As to fees on such applications see the Medicines (Products for Human Use--Fees) Regulations 1995, SI 1995/1116 (amended by SI 1996/683; SI 1998/574; SI 1999/566; SI 2000/592; SI 2000/3031; SI 2001/795; SI 2002/236; SI 2002/542; SI 2003/625; SI 2003/2321; SI 2004/666; SI 2004/1157; SI 2005/1124); and the Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750 (amended by SI 2004/3081).

UPDATE

78 Variation of licence on holder's application

TEXT AND NOTES--Replaced. The following provisions apply if the holder of a licence under the 1968 Act Pt II (ss 6-50) applies to the licensing authority for the licence to be varied: s 30(1) (s 30 substituted by the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005, SI 2005/2789). The application must (1) be in writing; (2) specify the required variation; (3) be signed by or on behalf of the applicant; (4) be accompanied by such information as is reasonably required to enable the licensing authority to consider the application; and (5) if there is a requirement in force under the Medicines Act 1971 s 1(1)(a) to pay a fee in respect of the application, be accompanied by the required fee: 1968 Act s 30(2) (s 30 as substituted). The licensing authority must consider any application properly made under this provision: s 30(3) (s 30 as substituted). If the variation would have the effect of altering (a) the types of medicinal product; (b) any operation carried out under the licence; (c) any premises; or (d) any equipment or facilities, in respect of which the licence was granted, the licensing authority must either vary the licence or refuse to vary it before the end of the period allowed for considering the application: s 30(4), (5) (s 30 as substituted). If the licensing authority considers that it is necessary for it to conduct an inspection of any premises to which the application relates, the period allowed is 90 days beginning with the date on which they receive the application: s 30(6) (s 30 as substituted). Otherwise, the period allowed is 90 days beginning with that date: s 30(7) (s 30 as substituted). The licensing authority may give the applicant written notice requiring him to give them such further information in

connection with the application as it considers reasonable: s 30(8) (s 30 as substituted). The period allowed for consideration stops running when a notice is given under s 30(8) and does not start running again until the licensing authority receives the information, or the applicant has shown to the reasonable satisfaction of the licensing authority why he is unable to provide it: s 30(9) (s 30 as substituted). Nothing in s 30 (as substituted) affects the powers conferred by s 28 (see PARA 70); s 30(10) (s 30 as substituted).

NOTE 7--SI 1995/1116 replaced: see now the Medicines (Products for Human Use) (Fees) Regulations 2009, SI 2009/389 (amended by SI 2009/3222).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(4) LICENCES AND LICENSING/(vii) Challenging the Decision of the Licensing Authority/79. Questioning the decision of the licensing authority.

(vii) Challenging the Decision of the Licensing Authority

79. Questioning the decision of the licensing authority.

The validity of any decision¹ of the licensing authority² and the validity of any licence³ or certificate⁴ granted or issued or other thing done in pursuance of any such decision may not be questioned⁵ in any legal proceedings except in specific circumstances⁶.

If the person⁷ to whom such a decision relates desires to question the validity of the decision on the grounds that it is not within the powers of the Medicines Act 1968⁸ or that any of the requirements of the Act, or of any regulations made under the Act⁹, which are applicable to the matter to which the decision relates have not been complied with¹⁰, that person may, at any time within the period of three months¹¹ from the date on which notice of the decision is served on him¹², apply to the High Court¹³. On any such application, the court may by interim order suspend the operation of the decision until the final determination of the proceedings¹⁴ and, if satisfied that the decision is not within the powers of the Act, or that the applicant's interests have been substantially prejudiced by a failure to comply with the relevant requirements¹⁵, may quash the decision¹⁶.

1 le under the Medicines Act 1968 Pt II (ss 6-50) (as amended). See in particular s 20 (as amended) (decision to grant or refuse a licence: see PARA 61 ante), s 28 (as amended) (decision to suspend, revoke or vary a licence: see PARA 70 ante), and s 30 (decision to vary a licence on the holder's application: see PARA 78 ante).

2 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

3 As to the licensing provisions see PARA 44 et seq ante; and as to the grant of licences see PARA 61 ante.

4 As to the grant of certificates see PARAS 81, 130 post.

5 Although the original jurisdiction of the court to determine the issue thus appears to be excluded, it may still exercise a supervisory jurisdiction to ensure that the limits of the authority's exclusive jurisdiction are observed: see *Anisminic Ltd v Foreign Compensation Commission* [1969] 2 AC 147, [1969] 1 All ER 208, HL; and JUDICIAL REVIEW vol 61 (2010) PARA 655. See also the text and notes 7-16 infra.

6 Medicines Act 1968 s 107(1).

7 For the meaning of 'person' see PARA 21 note 7 ante.

8 Medicines Act 1968 s 107(2)(a).

9 As to the making of regulations see PARA 5 ante.

10 Medicines Act 1968 s 107(2)(b).

11 For the meaning of 'month' see PARA 22 note 15 ante.

12 As to the service of notices see PARA 37 note 8 ante.

13 Medicines Act 1968 s 107(2). For the procedure on such an application see CPR Pt 52; and CIVIL PROCEDURE vol 12 (2009) PARA 1684. As to the High Court of Justice in England and Wales see COURTS vol 10 (Reissue) PARA 602 et seq.

14 Medicines Act 1968 s 107(3)(a). In respect of the exercise of this power see *R v Secretary of State for Health, ex p Generics (UK) Ltd* (1997) 40 BMLR 90, CA.

15 le the requirements mentioned in the Medicines Act 1968 s 107(2)(b): see the text to notes 9-10 supra.

16 Ibid s 107(3)(b). In reviewing a decision of the licensing authority, the court is not required to substitute its assessment of the facts and scientific evidence relied on by the authority, nor is it required to take into account any scientific material coming to light after the authority's decision: Case C-120/97 *Upjohn Ltd v Licensing Authority established under the Medicines Act 1968* [1999] ECR I-223, 51 BMLR 206, ECJ.

Where a decision to grant a licence or certificate is quashed, any licence or certificate granted in pursuance of the decision is void and any proceedings on the application for the grant of the licence or certificate may be continued as if no such application had been made: Medicines Act 1968 s 107(4).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(4) LICENCES AND LICENSING/(viii) Notification/80. Notification of medicinal products effectively on the market.

(viii) Notification

80. Notification of medicinal products effectively on the market.

Before the end of the period of two years from the date on which a product licence¹, other than a licence of right², is granted, the holder of the licence³, in respect of each description of medicinal products⁴ to which the licence relates which is effectively on the market in the United Kingdom⁵ within that period, must notify to the licensing authority⁶ a date on which medicinal products of that description were effectively on that market⁷.

1 For the meaning of 'product licence' see PARA 44 note 5 ante.

2 As to licences of right see PARA 12 note 23 ante.

3 As to references to the holder of a licence see PARA 66 note 5 ante.

4 For the meaning of 'medicinal product' see PARA 7 ante. As to the description of medicinal products see PARA 7 note 33 ante.

5 As to the meaning of 'effectively on the market in the United Kingdom' see PARA 44 note 18 ante. For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

6 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

7 Medicines Act 1968 s 44(5).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(4) LICENCES AND LICENSING/(ix) Certificates for Exporters/81. Certificates for exporters of medicinal products.

(ix) Certificates for Exporters

81. Certificates for exporters of medicinal products.

On the application of any person¹ who proposes to export² medicinal products³ of any description⁴, the licensing authority⁵ may issue to him a certificate containing any such statement relating to medicinal products of that description as the authority considers appropriate having regard to any requirements⁶ which have effect in the country to which the products are to be exported⁷, to the provisions of the Medicines Act 1968 and to any licence granted or other thing done by virtue of the Act⁸, and to the provisions of the clinical trials regulations⁹ and to any authorisation granted or other thing done by virtue of those regulations¹⁰.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 For the meaning of 'export' see PARA 7 note 4 ante.

3 For the meaning of 'medicinal product' see PARA 7 ante.

4 As to the description of medicinal products see PARA 7 note 33 ante.

5 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

6 Ie whether having the force of law or not: Medicines Act 1968 s 50(a).

7 Ibid s 50(a).

8 Ibid s 50(b).

9 For the meaning of 'the clinical trials regulations' see PARA 9 note 10 ante.

10 Medicines Act 1968 s 50(c) (added by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 54, Sch 10 Pt 1 para 16). As to the right of an authorised person to enter premises to verify statements contained in an application see PARA 169 post; and as to the power to inspect and take samples for that purpose see PARA 170 post.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(5) CLINICAL TRIALS/(i) In general/82. Meanings of 'clinical trial' and 'sponsor'.

(5) CLINICAL TRIALS

(i) In general

82. Meanings of 'clinical trial' and 'sponsor'.

'Clinical trial' means any investigation in human subjects¹, other than a non-interventional trial², intended:

- 84 (1) to discover or verify the clinical, pharmacological or other pharmacodynamic effects of one or more medicinal products;
- 85 (2) to identify any adverse reactions³ to one or more such products; or
- 86 (3) to study absorption, distribution, metabolism and excretion of one or more such products,

with the object of ascertaining the safety or efficacy of those products⁴.

'Sponsor' means, in relation to a clinical trial, the person⁵ who takes responsibility for the initiation, management and financing, or for arranging the financing, of that trial⁶. If two or more persons take responsibility for those matters in relation to a clinical trial, those persons may take joint responsibility for carrying out the functions of the sponsor of that trial⁷ or allocate responsibility for carrying out the functions of the sponsor of that trial⁸.

In cases where responsibility is so allocated, one of those persons must be responsible for carrying out the functions of a sponsor in relation to authorisation for clinical trials and ethics committee opinion⁹ and must make the request¹⁰ for authorisation to conduct the trial¹¹. After the clinical trial has been authorised by the licensing authority¹², a different person may be specified as responsible for carrying out the functions of the sponsor¹³ by making a substantial amendment¹⁴ to the terms of a clinical trial authorisation¹⁵.

A person who is a sponsor of a clinical trial must be established in the European Community¹⁶, or have a legal representative who is so established¹⁷.

1 'Subject' means, in relation to a clinical trial, an individual, whether a patient or not, who participates in a clinical trial as a recipient of an investigational medicinal product or of some other treatment or product, or, without receiving any treatment or product, as a control: Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1). 'Investigational medicinal product' means a pharmaceutical form of an active substance or placebo being tested, or to be tested, or used, or to be used, as a reference in a clinical trial, and includes a medicinal product which has a marketing authorisation but is, for the purposes of the trial: (1) used or assembled (formulated or packaged) in a way different from the form of the product authorised under the authorisation; (2) used for an indication not included in the summary of product characteristics under the authorisation for that product; or (3) used to gain further information about the form of that product as authorised under the authorisation: reg 2(1). 'Pharmaceutical form of an active substance' includes any substance or article in relation to which the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031 (as amended) have effect by virtue of an order under the Medicines Act 1968 ss 104, 105 (both as amended) (which relate to the application of the Act to certain articles and substances which are not medicinal products: see PARA 9 ante): Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1). 'Medicinal product' means a medicinal product within the meaning given by EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 1, or any product which is not a medicinal product within the meaning given by art 1 but which is a medicinal product within the meaning given by the Medicines Act 1968 s 130 (as amended) (see PARA 7 ante): Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1). 'Marketing authorisation' means: (a) a marketing authorisation granted by the licensing authority under the

Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144 (as amended) (see PARA 20 et seq ante); (b) a marketing authorisation issued by the competent authority of an EEA state, other than the United Kingdom, in accordance with EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67); (c) a marketing authorisation granted by the European Commission under EC Council Regulation 2309/93 (OJ L214, 24.8.1993, p 1) (as amended) (see PARA 19 ante) or EC Parliament and Council Regulation 726/2004 (OJ L36, 30.4.2004, p 1); or (d) a product licence granted by the licensing authority for the purposes of the Medicines Act 1968 s 7 (as amended) (see PARA 44 ante): Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1) (definition amended by SI 2005/2759). 'EEA state' means a state which is a contracting party to the EEA Agreement; 'EEA Agreement' means the Agreement on the European Economic Area (Oporto, 2 May 1992; EC 7 (1992); Cm 2183) as adjusted by the Protocol (Brussels, 17 March 1993; EC 2 (1993); Cm 2183); and 'European Economic Area' means the European Economic Area created by the EEA Agreement: Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1). For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by reg 2(1). For the meaning of 'assemble' see PARA 112 note 4 post. For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

2 'Non-interventional trial' means a study of one or more medicinal products which have a marketing authorisation, where the following conditions are met: (1) the products are prescribed in the usual manner in accordance with the terms of that authorisation; (2) the assignment of any patient involved in the study to a particular therapeutic strategy is not decided in advance by a protocol but falls within current practice; (3) the decision to prescribe a particular medicinal product is clearly separated from the decision to include the patient in the study; (4) no diagnostic or monitoring procedures are applied to the patients included in the study, other than those which are ordinarily applied in the course of the particular therapeutic strategy in question; and (5) epidemiological methods are to be used for the analysis of the data arising from the study: *ibid* reg 2(1). 'Protocol' means a document that describes the objectives, design, methodology, statistical considerations and organisation of a clinical trial: reg 2(1).

3 For the meaning of 'adverse reaction' see PARA 108 note 3 post.

4 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1).

5 For the meaning of 'person' see PARA 21 note 7 ante.

6 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, regs 2(1), 3(1).

7 *Ibid* reg 3(2)(a). If two or more persons take joint responsibility in accordance with reg 3(2)(a), any reference to the sponsor must, in relation to that trial, be construed as a reference to those persons (reg 3(3)(a)); and the provisions of reg 3(4)-(10) (see the text to notes 9-15 *infra*) do not apply (reg 3(3)(b)).

8 *Ibid* reg 3(2)(b). Such allocation must be in accordance with the provisions of reg 3(4)-(10) (see the text to notes 9-15 *infra*): reg 3(3)(b).

9 *Ie* under *ibid* Pt 3 (regs 11-27): see PARA 90 et seq post.

10 *Ie* in accordance with *ibid* reg 17: see PARA 95 post.

11 *Ibid* reg 3(4). The request for authorisation must specify: (1) who is responsible for carrying out the functions of the sponsor under Pt 3 (*ie* authorisation for clinical trials and ethics committee opinion) (reg 3(5)(a)); (2) who is to be responsible for carrying out the functions of the sponsor under Pt 4 (regs 28-31) (*ie* goods clinical practice and the conduct of clinical trials: see PARA 104 et seq post) (reg 3(5)(b)); and (3) who is to be responsible for carrying out the functions of the sponsor under Pt 5 (regs 32-35) (*ie* pharmacovigilance: see PARA 108 et seq post) (reg 3(5)(c)).

Where a person is responsible for carrying out the functions of the sponsor under Pt 3 by virtue of reg 3(5), or is specified in accordance with reg 3(6) (see the text to notes 12-15 *infra*) as responsible for those functions, any reference to the sponsor in that Part (except reg 15) (see PARA 93 post), Sch 3 Pts 2-4 (see PARAS 95, 101, 111 post), Sch 5 (see PARA 103 post) in so far as it relates to decisions of the licensing authority under Pt 3, and Sch 12 (transitional provisions), must, in relation to the trial, be construed as a reference to that person: reg 3(7). Where a person is specified in accordance with reg 3(5) or reg 3(6) as responsible for carrying out the functions of the sponsor under Pt 4, any reference to the sponsor in that Part (except reg 28(1)) (see PARA 104 post), or Sch 5 in so far as it relates to notices under reg 31(1) (see PARA 107 post), must, in relation to the trial, be construed as a reference to that person: reg 3(8). Where a person is specified in accordance with reg 3(5) or reg 3(6) as responsible for carrying out the functions of the sponsor under Pt 5, any reference to the sponsor in that Part must, in relation to the trial, be construed as a reference to that person: reg 3(9). Any reference to the sponsor in reg 15, reg 28(1), Pts 2, 6-9 (regs 36-56) (see PARA 112 et seq post), Sch 1 (see PARA 104 post), Sch 3 Pt 1 (see PARA 92 post), and Sch 7 (see PARA 115 post), must, in relation to the trial, include a reference to a person specified in accordance with reg 3(5) or reg 3(6): reg 3(10).

12 *Ie* in accordance with *ibid* regs 18-20: see PARAS 96-98 post.

- 13 Ie under ibid Pt 3, 4 or 5.
- 14 Ie in accordance with ibid regs 24-26: see PARAS 101-103 post.
- 15 Ibid reg 3(6). See also note 11 supra.
- 16 Ibid reg 3(11)(a).
- 17 Ibid reg 3(11)(b).

UPDATE

82 Meanings of 'clinical trial' and 'sponsor'

TEXT AND NOTES--The sponsor of a clinical trial must (1) ensure that the investigator's brochure for that trial, and any update of that brochure, presents the information it contains in a concise, simple, objective, balanced and non-promotional form that enables a clinician or potential investigator to understand it and make an unbiased risk-benefit assessment of the appropriateness of the proposed clinical trial; and (2) validate and update the investigator's brochure at least once a year: SI 2004/1031 reg 3A (added by SI 2006/1928). It is an offence to contravene SI 2004/1031 reg 3A: reg 49(1)(a) (reg 49(1) amended by SI 2006/1928).

NOTE 1--'EEA state' means a member state, Norway, Iceland or Liechtenstein: SI 2004/1031 reg 2(1) (definition replaced by SI 2006/1928).

TEXT AND NOTES 16, 17--For 'European Community' read 'EEA state': SI 2004/1031 reg 3(11)(a) (amended by SI 2006/1928). A person who is a sponsor of a clinical trial in accordance with SI 2004/1031 reg 3 may delegate any or all of his functions under SI 2004/1031 to any person but any such arrangement does not affect the responsibility of the sponsor: reg 3(12) (added by SI 2006/1928).

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83. Competent authority.

The competent authority¹ of the United Kingdom² is the licensing authority³. Except where any functions fall to be performed by the exercise of any powers or duties conferred⁴ on a person or body other than the licensing authority⁵, the licensing authority must perform, as respects the United Kingdom, the functions⁶ of the member state⁷.

1 Ie for the purposes of EC Parliament and Council Directive 2001/20 (OJ L121, 1.5.2001, p 34) on the approximation of the laws, regulations and administrative provisions of the member states relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use: Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1), 4(1). For the meaning of 'member state' see the European Communities Act 1972 s 1(2), Sch 1 Pt II; and the Interpretation Act 1978 s 5, Sch 1.

2 For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

3 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 4(1). For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by reg 2(1).

4 Ie by any provision of the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031 (as amended), or by any provision of the Medicines Act 1968 as applied by those regulations: Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 4(3).

5 Ibid reg 4(3).

6 Ie under EC Parliament and Council Directive 2001/20 (OJ L121, 1.5.2001, p 34).

7 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 4(2).

UPDATE

83 Competent authority

NOTE 1--The licensing authority is also the licensing authority for the purposes of EC Commission Directive 2005/28: SI 2004/1031 regs 2(1), 4(1) (amended by SI 2006/1928).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(5) CLINICAL TRIALS/(ii) Ethics Committees/84. United Kingdom Ethics Committees Authority.

(ii) Ethics Committees

84. United Kingdom Ethics Committees Authority.

The body responsible for establishing, recognising and monitoring ethics committees¹ in the United Kingdom² is the United Kingdom Ethics Committees Authority³. The Authority consists of the Secretary of State for Health, the National Assembly for Wales, the Scottish Ministers, and the Department for Health, Social Services and Public Safety for Northern Ireland⁴. The Authority must monitor the extent to which ethics committees adequately perform their functions⁵, and may provide advice and assistance to ethics committees with respect to the performance of their functions⁶.

The Authority may appoint such persons as it thinks necessary for the proper discharge by it of its functions; and those persons may be appointed on such terms and conditions, including conditions as to remuneration, benefits, allowances and reimbursement for expenses, as the Authority think fit⁷. Arrangements may be made between the Authority and any relevant authority⁸ for any functions of the Authority to be exercised by, or by members of staff of, the relevant authority⁹, or for the provision of staff, premises or administrative services by the relevant authority to the Authority¹⁰.

1 For the meaning of 'ethics committee' see PARA 85 note 2 post.

2 For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

3 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 5(1). As to the establishment and recognition of ethics committees see PARA 85 post.

4 Ibid reg 5(1)(a)-(d). As to the Secretary of State for Health see CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARA 464. As to the National Assembly for Wales and the Scottish Ministers see CONSTITUTIONAL LAW AND HUMAN RIGHTS.

The functions of the Authority: (1) may, by agreement between them, be performed by any one of the Secretary of State for Health, the National Assembly for Wales, the Scottish Ministers and the Department for Health, Social Services and Public Safety for Northern Ireland acting alone, or any two or more of them acting jointly (reg 5(2)(a)); and (2) may be performed by any one of the Secretary of State for Health, the National Assembly for Wales, the Scottish Ministers and the Department for Health, Social Services and Public Safety for Northern Ireland acting alone solely in relation to a part of the United Kingdom with respect to which the Secretary of State, the Assembly, the Ministers or the Department, as the case may be, have responsibilities (reg 5(2)(b)). In the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031 (as amended), the United Kingdom Ethics Committees Authority is referred to as 'the Authority', which means any one or more of the Secretary of State for Health, the National Assembly for Wales, the Scottish Ministers and the Department for Health, Social Services and Public Safety for Northern Ireland, and, in the case of anything falling to be done by the Authority, means any one or more of them acting as mentioned in reg 5(2): reg 5(3).

5 Ibid reg 10(1).

6 Ibid reg 10(2).

7 Ibid reg 5(4).

8 'Relevant authority' means any government department, local or public authority or holder of public office: ibid reg 5(7).

9 Ibid reg 5(5)(a). Any such arrangements for the exercise of any functions of the Authority do not affect the responsibility of the Authority: reg 5(6).

10 Ibid reg 5(5)(b).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(5) CLINICAL TRIALS/(ii) Ethics Committees/85. Establishment and recognition of ethics committees.

85. Establishment and recognition of ethics committees.

The United Kingdom Ethics Committees Authority¹ may establish ethics committees² to act for the entire United Kingdom³ or for such areas of the United Kingdom⁴, and in relation to such descriptions or classes of clinical trials⁵, as the Authority considers appropriate⁶. The Authority may vary the area for which any committee it has established acts or, as the case may be, the descriptions or classes of clinical trials in relation to which such a committee acts⁷, and may abolish any such committee⁸.

The Authority may, by a notice in writing, recognise a committee as an ethics committee if an application in relation to that committee has been made⁹ and it is satisfied that the proposed arrangements for the membership¹⁰ and operation of that ethics committee would enable that committee to perform the functions of an ethics committee adequately¹¹, and comply with other provisions¹² relating to such committees¹³. When recognising a committee, the Authority must specify whether the committee may act for the entire United Kingdom or only for a particular area of the United Kingdom¹⁴, the description or class of clinical trial in relation to which it may act as an ethics committee¹⁵, and any other conditions or limitations that apply to that committee¹⁶. The Authority may, where it considers it necessary or appropriate to do so, vary the area for which a recognised committee acts¹⁷, vary the description or class of clinical trial in relation to which it may act as an ethics committee¹⁸, or vary or revoke any conditions or limitations imposed¹⁹. The Authority may revoke a recognition of an ethics committee if it is satisfied that specified provisions²⁰ are not complied with in relation to that committee²¹, the committee is failing to perform its functions adequately or at all²², or it is otherwise necessary or expedient to do so²³.

Where recognition of an ethics committee is revoked²⁴, abolished or ceases operation²⁵, if the person²⁶ who was the appointing authority²⁷ before revocation, abolition or the ceasing of operation of the committee (known as 'the old committee') is the Authority, that person may nominate another ethics committee as responsible for the work of the committee²⁸, and if the person was not the Authority, that person may only nominate an ethics committee with the approval of the Authority²⁹. Where an ethics committee is nominated, that committee must consider any applications made³⁰ to the old committee, if the old committee had not given an opinion before the date of revocation, abolition or ceasing of operation³¹; and it is the relevant ethics committee for any clinical trial in relation to which the old committee had given³² a favourable opinion³³.

1 As to the United Kingdom Ethics Committees Authority see PARA 84 ante.

2 'Ethics committee' means: (1) a committee established or recognised in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, Pt 2 (regs 5-10); (2) the ethics committee constituted by regulations made by the Scottish Ministers under the Adults with Incapacity (Scotland) Act 2000 s 51(6); or (3) the gene therapy advisory committee: Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1). 'The gene therapy advisory committee' means the gene therapy advisory committee appointed by the Secretary of State to consider and advise on the acceptability of proposals for gene therapy research on human subjects, on ethical grounds, and provide advice on developments in gene therapy research and their implications: reg 2(1). As to the Secretary of State see PARA 3 note 3 ante. As to the Scottish Ministers see CONSTITUTIONAL LAW AND HUMAN RIGHTS.

3 For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

4 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 6(1)(a).

- 5 Ibid reg 6(1)(b). For the meaning of 'clinical trial' see PARA 82 ante.
- 6 Ibid reg 6(1). As to the expenses of ethics committees see PARA 89 post.
- 7 Ibid reg 6(2)(a).
- 8 Ibid reg 6(2)(b).
- 9 Ibid reg 7(1)(a). An application for recognition of an ethics committee must be made in writing to the Authority (reg 7(2)(a)), and accompanied by such information, documents and particulars as are necessary to enable the Authority to determine the application (reg 7(2)(b)). If any committee was established or recognised by the Secretary of State, the Scottish Ministers, the National Assembly for Wales, the Department of Health, Social Services and Public Safety, or by a strategic health authority, health board or health and social services board, for the purpose of advising on the ethics of research investigations on human beings (reg 7(3)(a)), and was in existence on 30 April 2004 (reg 7(3)(b)), the Authority may recognise that committee without an application for recognition being submitted (reg 7(3)). As to the National Assembly for Wales see CONSTITUTIONAL LAW AND HUMAN RIGHTS. 'Strategic health authority' means a strategic health authority established under the National Health Service Act 1977 (see HEALTH SERVICES vol 54 (2008) PARA 94 et seq); 'health board' means a health board established under the National Health Service (Scotland) Act 1978; and 'health and social services board' means a health and social services board established under the Health and Personal Social Services (Northern Ireland) Order 1972, SI 1972/1265 (NI 14); Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1).
- 10 As to the membership of ethics committees see PARA 86 post.
- 11 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 7(1)(b)(i).
- 12 Ie the provisions of ibid reg 9, Sch 2: see PARAS 86-89 post.
- 13 Ibid reg 7(1)(b)(ii).
- 14 Ibid reg 7(4)(a).
- 15 Ibid reg 7(4)(b).
- 16 Ibid reg 7(4)(c).
- 17 Ibid reg 7(5)(a).
- 18 Ibid reg 7(5)(b).
- 19 Ibid reg 7(5)(c).
- 20 Ie the provisions of ibid Sch 2: see PARAS 86-89 post.
- 21 Ibid reg 8(a).
- 22 Ibid reg 8(b).
- 23 Ibid reg 8(c).
- 24 Ibid reg 9, Sch 2 para 13(1)(a).
- 25 Ibid Sch 2 para 13(1)(b).
- 26 For the meaning of 'person' see PARA 21 note 7 ante.
- 27 If the person no longer exists or if that person fails to nominate another ethics committee, the Authority must nominate such a committee: Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, Sch 2 para 13(4). 'Appointing authority' means in relation to an ethics committee established under reg 6 (see the text to notes 1-8 supra), the Authority; in relation to an ethics committee recognised by the Authority after an application in accordance with reg 7(1) (see the text to notes 9-13 supra), the person who applied for recognition; or in relation to an ethics committee recognised without an application for recognition being submitted in accordance with reg 7(3) (see note 9 supra), the Authority: Sch 2 para 1.
- 28 Ibid Sch 2 para 13(2).

- 29 Ibid Sch 2 para 13(3).
30 le in accordance with ibid reg 14: see PARA 92 post.
31 Ibid Sch 2 para 13(5)(a).
32 le in accordance with ibid reg 15: see PARA 93 post.
33 Ibid Sch 2 para 13(5)(b).

UPDATE

85 Establishment and recognition of ethics committees

NOTE 2--Definition of 'gene therapy advisory committee' amended: SI 2008/941.

NOTE 19--SI 2004/1031 reg 7(5)(c) amended: SI 2006/1928.

NOTE 27--In relation to the Gene Therapy Advisory Committee, the Secretary of State is the appointing authority: SI 2004/1031 Sch 2 para 1 (amended by SI 2006/1928).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(5) CLINICAL TRIALS/(ii) Ethics Committees/86. Membership of ethics committees.

86. Membership of ethics committees.

An ethics committee¹ must consist of expert members² and lay members³, and must have no more than 18 members⁴. The members of an ethics committee, other than deputy members⁵, must be appointed by the appointing authority⁶. An appointing authority must, in relation to an ethics committee, exercise its power of appointment so as to ensure that at least one third of the total membership is lay members⁷, and at least half of the lay members are persons who are not, or who never have been, health care professionals⁸, persons involved in the conduct of clinical research, other than as a subject of such research⁹, or a chairman, member or director of a health service body¹⁰, or a body, other than a health service body, which provides health care¹¹. A member of an ethics committee holds and vacates office as a member in accordance with the terms of the instrument appointing him as a member¹².

The appointing authority must appoint one of the members of each ethics committee to be chairman of the committee¹³, another member to be vice-chairman¹⁴ and another member to be alternate vice-chairman¹⁵. The members appointed as chairman, vice-chairman and alternate vice-chairman must each be appointed for such period, not exceeding the remainder of his term as a member, as the appointing authority may specify on appointing him¹⁶. Any member so appointed may at any time resign from the office of chairman, vice-chairman or alternate vice-chairman¹⁷.

1 For the meaning of 'ethics committee' see PARA 85 note 2 ante.

2 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 9, Sch 2 para 3(1)(a). 'Expert member' means a member of an ethics committee who: (1) is a health care professional; (2) has professional qualifications or experience relating to the conduct of, or use of statistics in clinical trials, unless those professional qualifications or experience relate only to the ethics of clinical research or medical treatment; or (3) is not a health care professional, but has been a registered medical practitioner (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 4) or a person registered in the dentists register under the Dentists Act 1984 (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 417); Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, Sch 2 para 1. 'Health care professional' means a doctor, a dentist, a nurse, a pharmacist, a person registered in a register of ophthalmic opticians maintained under the Opticians Act 1989 s 7 (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 838), a person registered in a register established and maintained under Health Professions Order 2001, SI 2002/254, art 5 (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 325), a registered osteopath as defined by the Osteopaths Act 1993 s 41 (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 503), or a registered chiropractor as defined by the Chiropractors Act 1994 s 43 (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 595); 'doctor' means a registered medical practitioner; 'dentist' means a person registered in the dentists register under the Dentists Act 1984 or entered in the list of visiting EEA practitioners under Sch 4 (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 431); 'nurse' means a registered nurse or registered midwife (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 717); 'pharmacist' means a person registered in the register of pharmaceutical chemists established in pursuance of the Pharmacy Act 1952 and maintained in pursuance of the Pharmacy Act 1954 (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 888); Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1). For the meaning of 'clinical trial' see PARA 82 ante.

The provisions of the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, Sch 2 (other than Sch 2 para 13) (see PARA 85 ante) do not apply before 1 May 2005 in relation to an ethics committee established or recognised solely for the purpose of considering Phase I trials: Sch 2 para 2(2). 'Phase I trial' means a clinical trial to study the pharmacology of an investigational medicinal product when administered to humans, where the sponsor and investigator have no knowledge of any evidence that the product has effects likely to be beneficial to the subjects of the trial: reg 2(1). For the meaning of 'sponsor' see PARA 82 ante. For the meanings of 'investigational medicinal product' and 'subject' see PARA 82 note 1 ante. 'Investigator' means, in relation to a clinical trial, the authorised health professional responsible for the conduct of that trial at a trial site, and if the trial is conducted by a team of authorised health professionals at a trial site, the investigator is the leader responsible for that team: reg 2(1). 'Authorised health professional' means a doctor, a dentist, a

nurse, or a pharmacist: reg 2(1). 'Conducting a clinical trial' includes: (a) administering, or giving directions for the administration of, an investigational medicinal product to a subject for the purposes of that trial; (b) giving a prescription for an investigational medicinal product for the purposes of that trial; (c) carrying out any other medical or nursing procedure in relation to that trial; and (d) carrying out any test or analysis to discover or verify the clinical, pharmacological or other pharmacodynamic effects of the investigational medicinal products administered in the course of the trial, to identify any adverse reactions to those products, or to study absorption, distribution, metabolism and excretion of those products, but does not include any activity undertaken prior to the commencement of the trial which consists of making such preparations for the trial as are necessary or expedient: reg 2(1). 'Trial site' means a hospital, health centre, surgery or other establishment or facility at or from which a clinical trial, or any part of such a trial, is conducted: reg 2(1). 'Hospital' includes a clinic, nursing home or similar institution; and 'health centre' means a health centre maintained under the National Health Service Act 1977 ss 2, 3 (see HEALTH SERVICES vol 54 (2008) PARA 10 et seq), the National Health Service (Scotland) Act 1978 s 36 or the Health and Personal Social Services (Northern Ireland) Order 1972, SI 1972/1265 (NI 14); Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1). For the meaning of 'adverse reaction' see PARA 108 note 3 post.

3 Ibid Sch 2 para 3(1)(b). 'Lay member' means a member of an ethics committee, other than an expert member: Sch 2 para 1. A person is not eligible for appointment as a lay member of an ethics committee if, in the course of his employment or business, he provides medical, dental or nursing care (Sch 2 para 3(4)(a)), or conducts clinical research (Sch 2 para 3(4)(b)). As to the exception of co-opted members in relation to this provision see PARA 87 note 18 post.

4 Ibid Sch 2 para 3(2). As to the exception of co-opted members in relation to this provision see PARA 87 note 18 post. As to the payment of expenses and allowances to members see PARA 89 post.

5 An ethics committee may appoint a person to act as the deputy of an expert member or a lay member provided that the person would be eligible for appointment as an expert member or, as the case may be, a lay member: ibid Sch 2 para 7(1). A deputy holds and vacates office as a deputy member in accordance with the terms of the instrument appointing him as a deputy (Sch 2 para 7(2)), and may vote as a member of the committee only if the member for which he acts as deputy is absent (Sch 2 para 7(3)). A deputy member and the member for which he is deputy count as one member for the purposes of Sch 2 para 3(2) (see the text to note 4 supra), Sch 2 para 3(4) (see note 3 supra), Sch 2 para 6(4) (see PARA 87 post): Sch 2 para 7(4).

6 Ibid Sch 2 para 3(3). For the meaning of 'appointing authority' see PARA 85 note 27 ante.

7 Ibid Sch 2 para 3(5)(a).

8 Ibid Sch 2 para 3(5)(b)(i).

9 Ibid Sch 2 para 3(5)(b)(ii).

10 Ibid Sch 2 para 3(5)(b)(iii)(aa). 'Health service body' means: (1) a strategic health authority, health board or health and social services board; (2) a special health authority, primary care trust or local health board established under the National Health Service Act 1977; (3) a special health board established under the National Health Service (Scotland) Act 1978; (4) a special health and social services agency established under the Health and Personal Social Services (Special Agencies) (Northern Ireland) Order 1990, SI 1990/247 (NI 3); (5) the dental practice board constituted under the National Health Service Act 1977 s 37(1); (6) the Scottish dental practice board or the common services agency for the Scottish health service established under the National Health Service (Scotland) Act 1978; (7) the Northern Ireland Central Services Agency for the Health and Social Services established under the Health and Personal Social Services (Northern Ireland) Order 1972, SI, 1972/1265 (NI 14); (8) a national health service trust established under the National Health Service and Community Care Act 1990 or the National Health Service (Scotland) Act 1978; (9) an NHS foundation trust within the meaning of the Health and Social Care (Community Health and Standards) Act 2003 s 1(1) (see HEALTH SERVICES vol 54 (2008) PARA 174 et seq); or (10) a health and social services trust established under the Health and Personal Social Services (Northern Ireland) Order 1991, SI 1991/194 (NI 1); Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1). For the meanings of 'strategic health authority', 'health board' and 'health and social services board' see PARA 85 note 9 ante. See further HEALTH SERVICES vol 54 (2008) PARA 74 et seq.

11 Ibid Sch 2 para 3(5)(b)(iii)(bb). 'Health care' means services for or in connection with the prevention, diagnosis or treatment of illness: reg 2(1).

12 Ibid Sch 2 para 4.

13 Ibid Sch 2 para 5(1)(a). Where the chairman has died or has ceased to hold office, or where he is unable to perform his duties as chairman owing to illness, absence or any other cause, references to the chairman must, so long as there is no chairman available to perform his duties, be taken to include references to: (1) the vice-chairman (Sch 2 para 5(4)(a)); (2) if the vice-chairman is also unable to perform his duties, the alternate

vice-chairman (Sch 2 para 5(4)(b)); or (3) if all three individuals are unavailable, a member appointed by the appointing authority for the purposes of acting as chairman until one of those individuals is available to perform his duties (Sch 2 para 5(4)(c)).

14 Ibid Sch 2 para 5(1)(b). See also note 13 supra.

15 Ibid Sch 2 para 5(1)(c). See also note 13 supra.

16 Ibid Sch 2 para 5(2).

17 Ibid Sch 2 para 5(3).

UPDATE

86 Membership of ethics committees

NOTE 2--Definition of 'pharmacist' amended: SI 2007/289. Definition of 'health care professional' substituted: SI 2007/3101. Definition of 'expert member' amended: SI 2008/941.

TEXT AND NOTE 5--SI 2004/1031 Sch 2 para 7(1) amended: SI 2008/941.

NOTE 6--SI 2004/1031 Sch 2 para 3(3) amended: SI 2008/941.

NOTE 10--Head (5) omitted: SI 2004/1031 reg 2(1) (amended by SI 2006/562).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(5) CLINICAL TRIALS/(ii) Ethics Committees/87. Meetings and sub-committees.

87. Meetings and sub-committees.

An ethics committee¹ must, subject to approval by the United Kingdom Ethics Committees Authority², make standing orders and adopt standing operating procedures for the regulation of its proceedings and business³, and may, subject to approval by the Authority, vary or revoke such orders or procedures⁴. An ethics committee may appoint sub-committees consisting of members of the committee⁵, and make arrangements for the exercise, on behalf of the committee, of any of its functions by such a sub-committee⁶, in accordance with the adopted standing orders and operating procedures⁷.

The meetings and proceedings of an ethics committee and its sub-committees must be conducted in accordance with the standing orders made and standing operating procedures adopted by it⁸. However, no business may be transacted at a meeting of an ethics committee, or a sub-committee of an ethics committee, to determine⁹ the opinion of an ethics committee in relation to a clinical trial¹⁰, unless at least seven members of the committee, including any co-opted members, are present, including at least one lay member¹¹ who is not and never has been a health care professional¹² or a chairman, member, director, officer or employee of a health service body¹³, and one expert member¹⁴.

At any meeting of an ethics committee, the committee may co-opt up to two additional members for the purposes of that meeting¹⁵; and at any meeting of a sub-committee of an ethics committee, the sub-committee may co-opt an additional member for the purposes of that meeting¹⁶. A person is eligible to be co-opted as a member only if he is or has been a member of an ethics committee¹⁷. A co-opted member holds office only in relation to the meeting for which he is co-opted¹⁸.

1 For the meaning of 'ethics committee' see PARA 85 note 2 ante.

2 As to the United Kingdom Ethics Committees Authority see PARA 84 ante.

3 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 9, Sch 2 para 6(3)(a). Standing orders and operating procedures may include provision for the suspension of the standing orders or operating procedures or any of them: Sch 2 para 6(3). As to the application of Sch 2 see PARA 86 note 2 ante.

4 Ibid Sch 2 para 6(3)(b).

5 Ibid Sch 2 para 6(1)(a). As to membership of ethics committees see PARA 86 ante.

6 Ibid Sch 2 para 6(1)(b).

7 Ibid Sch 2 para 6(1).

8 Ibid Sch 2 para 6(2).

9 Ie in accordance with ibid reg 15: see PARA 93 post.

10 For the meaning of 'clinical trial' see PARA 82 ante.

11 For the meaning of 'lay member' see PARA 86 note 3 ante.

12 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, Sch 2 para 6(4)(a)(i). For the meaning of 'health care professional' see PARA 86 note 2 ante.

13 Ibid Sch 2 para 6(4)(a)(ii). For the meaning of 'health service body' see PARA 86 note 10 ante.

14 Ibid Sch 2 para 6(4)(b). For the meaning of 'expert member' see PARA 86 note 2 ante.

15 Ibid Sch 2 para 8(1).

16 Ibid Sch 2 para 8(2).

17 Ibid Sch 2 para 8(3). This provision does not apply in relation to the gene therapy advisory committee: Sch 2 para 8(4). For the meaning of 'the gene therapy advisory committee' see PARA 85 note 2 ante.

18 Ibid Sch 2 para 8(5). A co-opted member does not count as a member for the purposes of Sch 2 para 3(2), (4) (see PARA 86 ante): Sch 2 para 8(6).

UPDATE

87 Meetings and sub-committees

NOTE 8--SI 2004/1031 Sch 2 para 6(2) amended: SI 2008/941.

TEXT AND NOTES 12-14--SI 2004/1031 Sch 2 para 6(4) substituted, Sch 2 para 6(6) added: SI 2008/941.

TEXT AND NOTE 14--An ethics committee must retain all the documents relating to a clinical trial on which it gives an opinion for (1) where the trial proceeds, at least three years from the conclusion of the trial; or (2) where the trial does not proceed, at least three years from the date of the opinion: SI 2004/1031 Sch 2 para 6(5) (added by SI 2006/1928).

TEXT AND NOTE 17--A person is eligible to be co-opted as a member only if he is or has been a member of a committee that advises or has advised on the ethics of research involving human subjects: SI 2004/1031 Sch 2 para 8(3) (amended by SI 2008/941).

TEXT AND NOTE 18--A co-opted member is to hold and vacate office in accordance with the ethics committee's standing orders and operating procedures adopted under SI 2004/1031 Sch 2 para 6(3): Sch 2 para 8(5) (substituted by SI 2008/941).

NOTE 18--A co-opted member does not count as a member for the purposes of SI 2004/1031 Sch 2 para 3(2), (5): Sch 2 para 8(6) (amended by SI 2006/1928).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(5) CLINICAL TRIALS/(ii) Ethics Committees/88. Staff, premises and facilities.

88. Staff, premises and facilities.

The appointing authority¹ must make arrangements for the appointment of such administrative and other staff for an ethics committee² as it considers necessary to enable the committee to perform its functions³. The appointing authority must secure the provision to an ethics committee of such accommodation and facilities as it considers necessary to enable the committee to perform its functions⁴, and secure that arrangements are made for such administration, maintenance, cleaning and other services as may, in its opinion, be necessary for such accommodation and facilities⁵. To enable an ethics committee to perform its functions, a health service body⁶ may make staff, premises and facilities available to an ethics committee under arrangements made with the appointing authority⁷.

1 For the meaning of 'appointing authority' see PARA 85 note 27 ante.

2 For the meaning of 'ethics committee' see PARA 85 note 2 ante.

3 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 9, Sch 2 para 9(1). As to the application of Sch 2 see PARA 86 note 2 ante. As to the establishment and recognition of ethics committees see PARA 85 ante.

4 Ibid Sch 2 para 9(2)(a).

5 Ibid Sch 2 para 9(2)(b).

6 For the meaning of 'health service body' see PARA 86 note 10 ante.

7 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, Sch 2 para 9(3).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(5) CLINICAL TRIALS/(ii) Ethics Committees/89. Expenses; annual report.

89. Expenses; annual report.

The appointing authority¹ must, in respect of each financial year², pay to an ethics committee³ sums equal to the amount approved as the amounts of expenditure which it considers may be reasonably incurred by the committee in that year for the purpose of performing its functions⁴. An ethics committee must not incur expenses in excess of the amounts approved for that committee by the appointing authority⁵. The appointing authority may pay to members of ethics committees⁶ such travelling and other allowances as the authority may determine⁷.

Within the period six months⁸ from the end of each financial year, every ethics committee must prepare a report on the committee's activities during that year, which must include a list of the applications made⁹ to the committee¹⁰, and the decisions made by the committee in relation to those applications¹¹. The committee must send a copy of the report to the United Kingdom Ethics Committees Authority¹² and, if the Authority is not the appointing authority for that committee, to its appointing authority¹³.

1 For the meaning of 'appointing authority' see PARA 85 note 27 ante.

2 'Financial year' means the 12 months ending with 31 March: Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 9, Sch 2 para 1.

3 For the meaning of 'ethics committee' see PARA 85 note 2 ante.

4 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, Sch 2 para 10(1). As to the application of Sch 2 see PARA 86 note 2 ante. As to the establishment and recognition of ethics committees see PARA 85 ante.

5 Ibid Sch 2 para 10(2).

6 As to the membership of ethics committees see PARA 86 ante.

7 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, Sch 2 para 11.

8 For the meaning of 'month' see PARA 22 note 15 ante.

9 Ie in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 14: see PARA 92 post.

10 Ibid Sch 2 para 12(1)(a).

11 Ibid Sch 2 para 12(1)(b).

12 As to the United Kingdom Ethics Committees Authority see PARA 84 ante.

13 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, Sch 2 para 12(2).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(5) CLINICAL TRIALS/(iii) Ethics Committee Opinion and Authorisation for Clinical Trials/A. IN GENERAL/90. Requirement for authorisation and ethics committee opinion.

(iii) Ethics Committee Opinion and Authorisation for Clinical Trials

A. IN GENERAL

90. Requirement for authorisation and ethics committee opinion.

No person¹ may start a clinical trial² or cause a clinical trial to be started³, or conduct a clinical trial⁴, unless the following conditions are satisfied⁵: (1) an ethics committee⁶ or an appeal panel⁷ has given a favourable opinion in relation to the clinical trial⁸; and (2) the clinical trial has been authorised by the licensing authority⁹.

No person may recruit an individual to be a subject¹⁰ in a trial¹¹, or issue an advertisement for the purpose of recruiting individuals to be subjects in a trial¹², unless condition (1) above has been satisfied¹³.

It is an offence to contravene these provisions¹⁴.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 For the meaning of 'clinical trial' see PARA 82 ante.

3 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 12(1)(a).

4 Ibid reg 12(1)(b). As to the meaning of 'conducting a clinical trial' see PARA 86 note 2 ante.

5 Ibid reg 12(1).

6 For the meaning of 'ethics committee' see PARA 85 note 2 ante.

7 I.e. appointed under the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 16(6), Sch 4: see PARA 94 post.

8 Ibid reg 12(3)(a). As to ethics committee opinions see PARA 92 et seq post.

9 Ibid reg 12(3)(b). For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by reg 2(1). For these purposes, a clinical trial has been authorised by the licensing authority if:

59 (1) in the case of a trial to which reg 18 (see PARA 96 post) relates:

9. (a) the trial is to be treated as authorised by virtue of reg 18 (reg 12(4)(a)(i)); or
9

10. (b) the authority has accepted the request for authorisation in accordance with the procedure specified in Sch 5 (see PARA 103 post) (reg 12(4)(a)(ii)); or
10

60 (2) in the case of a clinical trial to which reg 19 (see PARA 97 post) or reg 20 (see PARA 98 post) applies:

11. (a) the authority has given a notice of authorisation in accordance with those regulations (reg 12(4)(b)(i)); or
11

12. (b) the authority has accepted the request for authorisation in accordance with the procedure specified in Sch 5 (reg 12(4)(b)(ii)).
12

- 10 For the meaning of 'subject' see PARA 82 note 1 ante.
- 11 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 12(2)(a).
- 12 Ibid reg 12(2)(b).
- 13 Ibid reg 12(2).
- 14 Ibid reg 49(1)(a). As to offences generally, defences and penalties see PARAS 123-125 post.

UPDATE

90 Requirement for authorisation and ethics committee opinion

NOTE 8--SI 2004/1031 reg 12(3)(a) amended: SI 2006/1928.

NOTE 14--Now SI 2004/1031 reg 49(1)(aa) (amended by SI 2006/1928).

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91. Supply of investigational medicinal products for clinical trials.

No person¹ may, in the course of a business² carried on by him, sell or supply any investigational medicinal product³ to an investigator⁴, a health care professional⁵ who is a member of an investigator's team⁶, a person who provides or is to provide health care⁷ under the direction or control of an investigator or such a health care professional⁸, or a subject⁹, for the purpose of administering that product in a clinical trial¹⁰, unless certain conditions are satisfied¹¹. The conditions are that:

- 87 (1) the licensing authority¹² has authorised the clinical trial¹³ for the purposes of which the product is sold or supplied¹⁴;
- 88 (2) in the case of an investigational medicinal product manufactured¹⁵ or assembled¹⁶ in an EEA state¹⁷, other than in accordance with the terms of a marketing authorisation¹⁸ relating to that product, or imported into an EEA state:
 - 13 13. (a) the product has been manufactured, assembled or imported in accordance with the terms of a manufacturing authorisation¹⁹, or an authorisation²⁰ granted by a competent authority of an EEA state other than the United Kingdom²¹; and
 14. (b) the production batch of investigational medicinal products of which the product is a part has been checked and certified²² by a qualified person²³.

The restriction on the sale or supply of investigational medicinal products does not apply to the sale or supply of a medicinal product²⁴ in accordance with the terms of a marketing authorisation relating to that product, other than a marketing authorisation issued by the competent authority of an EEA state other than the United Kingdom²⁵.

It is an offence to contravene this restriction²⁶; and any person who has in his possession a medicinal product for the purpose of selling or supplying it in contravention of the restriction is also guilty of an offence²⁷.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 'Business' includes a professional practice and includes any activity carried on by a body of persons, whether corporate or unincorporate: Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1). As to bodies corporate see COMPANIES; CORPORATIONS.

3 For the meaning of 'investigational medicinal product' see PARA 82 note 1 ante.

4 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 13(1)(a). For the meaning of 'investigator' see PARA 86 note 2 ante.

5 For the meaning of 'health care professional' see PARA 86 note 2 ante.

6 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 13(1)(b).

7 For the meaning of 'health care' see PARA 86 note 11 ante.

8 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 13(1)(c).

- 9 Ibid reg 13(1)(d). For the meaning of 'subject' see PARA 82 note 1 ante.
- 10 For the meaning of 'clinical trial' see PARA 82 ante.
- 11 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 13(1).
- 12 For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by ibid reg 2(1).
- 13 As to the authorisation of clinical trials see PARA 95 et seq post.
- 14 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 13(2)(a).
- 15 As to the meaning of 'manufacture' see PARA 112 note 3 post.
- 16 For the meaning of 'assemble' see PARA 112 note 4 post.
- 17 For the meaning of 'EEA state' see PARA 82 note 1 ante.
- 18 For the meaning of 'marketing authorisation' see PARA 82 note 1 ante.
- 19 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 13(2)(b)(i)(aa). For the meaning of 'manufacturing authorisation' see PARA 112 note 6 post. If an investigational medicinal product has been manufactured or imported prior to 1 May 2004: (1) the condition specified in reg 13(2)(b)(i) applies only in relation to any assembly of that product which takes place on or after that date (reg 13(3)(a)); and (2) the conditions specified in reg 13(2)(b)(ii) (see the text to notes 22-23 infra) do not apply (reg 13(3)(b)).
- 20 Ie referred to in EC Parliament and Council Directive 2001/20 (OJ L121, 1.5.2001, p 34) art 13.
- 21 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 13(2)(b)(i)(bb). See also note 19 supra. For the meaning of 'United Kingdom' see PARA 7 note 3 ante.
- 22 Ie pursuant to EC Parliament and Council Directive 2001/20 (OJ L121, 1.5.2001, p 34) art 13(3), (4).
- 23 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 13(2)(b)(ii). See also note 19 supra. For the meaning of 'qualified person' see PARA 118 note 2 post.
- 24 For the meaning of 'medicinal product' see PARA 82 note 1 ante.
- 25 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 13(4).
- 26 Ibid reg 49(1)(b). As to offences generally, defences and penalties see PARAS 123-125 post.
- 27 Ibid reg 49(2).

UPDATE

91 Supply of investigational medicinal products for clinical trials

TEXT AND NOTE 21--After 'the United Kingdom' read '; or in the case of assembly only, under the exemption for hospitals and health centres' (as to which, see SI 2004/1031 reg 37 and PARA 112): reg 13(2)(b)(i)(cc) (reg 13(2)(b)(i) substituted by SI 2006/1928).

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B. ETHICS COMMITTEE OPINION

92. Application for ethics committee opinion.

An application for an ethics committee¹ opinion in relation to a clinical trial² must be made by the chief investigator³ for that trial⁴. A chief investigator for a trial must make an application for an ethics committee opinion in relation to that trial to one ethics committee only, regardless of the number of trial sites at which the trial is to be conducted⁵. The application must be made to an ethics committee established or recognised⁶ for the entire United Kingdom⁷, or in relation to an area of the United Kingdom in which the chief investigator is professionally based⁸, and in relation to a description or class of clinical trial into which the proposed trial falls⁹. An application must be in writing¹⁰, signed by the chief investigator making the application¹¹, and accompanied by the specified particulars and documents¹². The application and any accompanying material must be supplied in the English language¹³.

Any person¹⁴ who in the course of making an application for an ethics committee opinion provides to an ethics committee any relevant information¹⁵ which is false or misleading in a material particular is guilty of an offence¹⁶.

1 For the meaning of 'ethics committee' see PARA 85 note 2 ante.

2 For the meaning of 'clinical trial' see PARA 82 ante.

3 'Chief investigator' means, in relation to a clinical trial conducted at a single trial site, the investigator for that site or, in relation to a clinical trial conducted at more than one trial site, the authorised health care professional, whether or not he is an investigator at any particular site, who takes primary responsibility for the conduct of the trial: Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1). For the meanings of 'trial site', 'investigator', 'health care professional', and as to the meaning of 'conducting a clinical trial', see PARA 86 note 2 ante.

4 Ibid reg 14(1).

5 Ibid reg 14(2).

6 As to the establishment and recognition of ethics committees see PARA 85 ante.

7 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 14(3)(a)(i). For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

8 Ibid reg 14(3)(a)(ii). A chief investigator is professionally based at the hospital, health centre, surgery or other establishment or facility at or from which he primarily conducts his professional practice: reg 14(8). For the meanings of 'hospital' and 'health centre' see PARA 86 note 2 ante.

9 Ibid reg 14(3)(b). An application for an ethics committee opinion in relation to a clinical trial involving medicinal products for gene therapy must be made to the gene therapy advisory committee: reg 14(5). For the meaning of 'the gene therapy advisory committee' see PARA 85 note 2 ante.

10 Ibid reg 14(6)(a).

11 Ibid reg 14(6)(b). Any reference to an application, request or other document that is signed includes a reference to an application, request or other document that is signed with an electronic signature: reg 2(3). 'Electronic signature' means data in electronic form which are attached to or logically associated with other electronic data and which serve as a method of authentication: reg 2(1).

12 Ibid reg 14(6)(c). The specified particulars and documents are those specified Sch 3 Pt 1.

13 Ibid reg 14(7).

14 For the meaning of 'person' see PARA 21 note 7 ante.

15 'Relevant information' means any information which is relevant to an evaluation of: (1) the safety, quality or efficacy of an investigational medicinal product (Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 50(4)(a)); (2) the safety or scientific validity of a clinical trial (reg 50(4)(b)); or (3) whether, with regard to a clinical trial, the conditions and principles of good clinical practice are being satisfied or adhered to (reg 50(4)(c)). For the meaning of 'investigational medicinal product' see PARA 82 note 1 ante. For the meaning of 'the conditions and principles of good clinical practice' see PARA 104 note 5 post.

16 Ibid reg 50(1)(a). As to offences generally, defences and penalties see PARAS 123-125 post.

UPDATE

92 Application for ethics committee opinion

NOTE 3--In the definition of 'chief investigator', omit the word 'care': SI 2004/1031 reg 2(1) (amended by SI 2006/1928).

NOTE 12--SI 2004/1031 Sch 3 Pt 1 amended: SI 2008/941.

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93. Ethics committee opinion.

An ethics committee¹ must, within the specified period² following receipt of a valid application³, give an opinion in relation to the clinical trial to which the application relates⁴. Where, following receipt of a valid application, it appears to the committee that further information is required in order to give an opinion on a trial, the committee may, within the specified period and before giving its opinion, send a notice in writing to the applicant requesting that he furnishes the committee with that information⁵.

In preparing its opinion, the committee must consider, in particular, the following matters: (1) the relevance of the clinical trial and its design⁶; (2) whether the evaluation of the anticipated benefits and risks⁷ is satisfactory and whether the conclusions are justified⁸; (3) the protocol⁹; (4) the suitability of the investigator and supporting staff¹⁰; (5) the investigator's brochure¹¹; (6) the quality of the facilities for the trial¹²; (7) the adequacy and completeness of the written information to be given, and the procedure to be followed, for the purpose of obtaining informed consent¹³ to the subjects' participation in the trial¹⁴; (8) if the subjects are to include persons incapable of giving informed consent, whether the research is justified having regard to the specified¹⁵ conditions and principles¹⁶; (9) provision for indemnity or compensation in the event of injury or death attributable to the clinical trial¹⁷; (10) any insurance or indemnity¹⁸ to cover the liability of the investigator or sponsor¹⁹; (11) the amounts, and, where appropriate, the arrangements, for rewarding or compensating investigators and subjects²⁰; (12) the terms of any agreement between the sponsor and the owner or occupier of the trial site²¹ which are relevant to the arrangements referred to in head (11) above²²; and (12) the arrangements for the recruitment of subjects²³. The ethics committee must consider, and give an opinion on, any other issue relating to the clinical trial, if the committee has been asked by the applicant to consider the issue²⁴ or it is, in the committee's opinion, relevant to the other matters considered²⁵ by the committee²⁶.

Where an ethics committee gives an opinion it must publish a summary of that opinion²⁷.

1 For the meaning of 'ethics committee' see PARA 85 note 2 ante.

2 'The specified period' means: (1) in the case of a clinical trial involving a medicinal product for gene therapy or somatic cell therapy or a medicinal product containing a genetically modified organism where a specialist group or committee is consulted, 180 days, or where there is no such consultation, 90 days; or (2) in any other case, 60 days: Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 15(10). 'Specialist group or committee' means a group or committee whose functions include the provision of advice on ethical or scientific issues in relation to, in the case of medicinal products for gene therapy or somatic cell therapy, the use of such therapies in the treatment of humans or, in the case of medicinal products containing genetically modified organisms, the administration of such products to humans: reg 15(10). For the meaning of 'clinical trial' see PARA 82 ante. For the meaning of 'medicinal product' see PARA 82 note 1 ante.

3 'Valid application' means an application for an ethics committee opinion which complies with the provisions of *ibid* reg 14 (see PARA 92 ante): reg 11.

4 *Ibid* reg 15(1). If the clinical trial involves a medicinal product for xenogenic cell therapy, the time limits referred to in reg 15(1)-(3) do not apply and the ethics committee may give an opinion in relation to that trial or send a notice under reg 15(2) (see the text to note 5 *infra*) at any time after receipt of the valid application: reg 15(4).

5 *Ibid* reg 15(2). Where the committee sends such a request, the specified period is suspended pending receipt of the information requested: reg 15(3). As to the service of notices see PARA 37 note 8 ante; provision applied by reg 47(1). See also note 4 *supra*.

6 Ibid reg 15(5)(a).

7 Ie as required under ibid reg 2(1), Sch 1 Pt 2 para 2: see PARA 104 post.

8 Ibid reg 15(5)(b).

9 Ibid reg 15(5)(c). For the meaning of 'protocol' see PARA 82 note 2 ante.

10 Ibid reg 15(5)(d). For the meaning of 'investigator' see PARA 86 note 2 ante.

11 Ibid reg 15(5)(e). 'Investigator's brochure' means a document containing a summary of the clinical and non-clinical data relating to an investigational medicinal product which are relevant to the study of the product in human subjects: reg 2(1). For the meanings of 'investigational medicinal product' and 'subject' see PARA 82 note 1 ante.

12 Ibid reg 15(5)(f).

13 A person gives informed consent to take part, or that a subject is to take part, in a clinical trial only if his decision is given freely after that person is informed of the nature, significance, implications and risks of the trial, and either is evidenced in writing, dated and signed, or otherwise marked, by that person so as to indicate his consent, or if the person is unable to sign or to mark a document so as to indicate his consent, is given orally in the presence of at least one witness and recorded in writing; and references to 'informed consent' are to be construed accordingly and include references to informed consent given or refused by an adult unable by virtue of physical or mental incapacity to give informed consent, prior to the onset of that incapacity: ibid reg 2(1), Sch 1 para 3. As to references to 'signed' see PARA 92 note 11 ante. For these purposes, 'adult' means a person who has attained the age of 16 years: reg 2(1).

14 Ibid reg 15(5)(g).

15 Ie specified in ibid Sch 1 Pt 5: see PARA 104 post.

16 Ibid reg 15(5)(h). If any subject of the clinical trial is to be a minor (reg 15(6)(a)) and the committee does not have a member with professional expertise in paediatric care (reg 15(6)(b)), it must, before giving its opinion, obtain advice on the clinical, ethical and psychosocial problems in the field of paediatric care which may arise in relation to that trial (reg 15(6)). 'Minor' means a person under the age of 16 years: reg 2(1). If any subject of the clinical trial is to be an adult incapable by reason of physical and mental incapacity to give informed consent to participation in the trial (reg 15(7)(a)) and the committee does not have a member with professional expertise in the treatment of the disease to which the trial relates (reg 15(7)(b)(i)) and the patient population suffering that disease (reg 15(7)(b)(ii)), it must, before giving its opinion, obtain advice on the clinical, ethical and psychosocial problems in the field of that disease and patient population which may arise in relation to that trial (reg 15(7)).

17 Ibid reg 15(5)(i).

18 'Insurance or indemnity' includes provision for meeting losses or liabilities: (1) under a scheme established under the National Health Service and Community Care Act 1990 s 21 (schemes for meeting losses and liabilities etc of certain health service bodies in England and Wales), the National Health Service (Scotland) Act 1978 s 85B (schemes for meeting losses and liabilities etc of certain health service bodies in Scotland), or the Health and Personal Social Services (Northern Ireland) Order 1991, SI 1991/194 (NI 1) art 24 (schemes for meeting losses and liabilities etc of certain health service bodies in Northern Ireland); or (2) in accordance with guidance issued by the Secretary of State, the Scottish Ministers, the National Assembly for Wales, or the Department for Health, Social Services and Public Safety, as to the arrangements to be adopted by health service bodies for meeting the costs arising from clinical negligence (known as NHS Indemnity): Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1). As to the Secretary of State see PARA 3 note 3 ante. As to the Scottish Ministers and the National Assembly for Wales see CONSTITUTIONAL LAW AND HUMAN RIGHTS.

19 Ibid reg 15(5)(j). For the meaning of 'sponsor' see PARA 82 ante.

20 Ibid reg 15(5)(k).

21 For the meaning of 'trial site' see PARA 86 note 2 ante.

22 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 15(5)(l).

23 Ibid reg 15(5)(m).

24 Ibid reg 15(8)(a).

25 Ie in accordance with ibid reg 15.

26 Ibid reg 15(8)(b).

27 Ibid reg 15(9).

UPDATE

93 Ethics committee opinion

TEXT AND NOTES--SI 2004/1031 reg 15(4A), (4B) (removal of requirement on the Gene Therapy Advisory Committee to give an opinion) added: SI 2008/941.

TEXT AND NOTES 1-4--SI 2004/1031 reg 15(1) substituted, reg 15(3A), (3B) added: SI 2008/941.

NOTE 7--Now as required under SI 2004/1031 reg 2(1), Sch 1 Pt 2 para 10: reg 15(5)(b) (amended by SI 2006/1928).

TEXT AND NOTE 11--Now head (5) the investigator's brochure or, where the investigational medicinal product has a marketing authorization and the product is to be used in accordance with the terms of that authorization, the summary of product characteristics relating to that product: SI 2004/1031 reg 15(5)(e) (amended by SI 2006/1928).

TEXT AND NOTE 15--After 'are to include' read 'minors or': reg 15(5)(h) (amended by SI 2006/1928). The conditions and principles are now specified in SI 2004/1031 Sch 1 Pt 4 or Pt 5 respectively: reg 15(5)(h) (as so amended).

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94. Review and appeal relating to ethics committee opinion.

Where a chief investigator¹ for a trial has been notified by the ethics committee² to which he made an application³ that the committee's opinion in relation to that trial is not favourable⁴, except where the opinion was given by the gene therapy advisory committee⁵, the chief investigator may within 90 days of being notified that the committee's opinion is not favourable, give a notice to the United Kingdom Ethics Committees Authority stating his wish to appeal against the opinion⁶ and setting out his representations with respect to that opinion⁷. Where the Authority receives a notice⁸ that a chief investigator wishes to appeal against an ethics committee opinion which is not favourable, it must direct that the application for that opinion may be considered by another ethics committee specified in the direction⁹, or appoint an appeal panel¹⁰ and refer the opinion to that panel¹¹. However, except where the opinion was given by the gene therapy advisory committee¹², the Authority may refuse to give a direction or appoint a panel where it considers that the grounds for appealing against the opinion are unfounded¹³.

Where a direction is given that the application be considered by another ethics committee, the ethics committee which gave the unfavourable opinion must send to the ethics committee specified in the direction the application for that opinion¹⁴, and any additional information provided by the chief investigator¹⁵, and the committee specified in the direction must consider¹⁶ the application¹⁷.

An appeal panel must consider an ethics committee opinion referred to it¹⁸ by considering the opinion¹⁹, the application for that opinion²⁰, the particulars and documents accompanying that application²¹, specified matters²², any representations set out in the notice to the Authority²³, and, in a case where the opinion has been confirmed by the gene therapy advisory committee on a review²⁴, the reasons given by the committee for that confirmation²⁵. The panel may, if the chief investigator so requests, hold a hearing to consider the opinion, at which the chief investigator may make oral representations²⁶. The panel must within 30 days of the opinion being referred to it, or such extended period as the Authority may in any particular case allow, either confirm the opinion or give a favourable opinion²⁷.

1 For the meaning of 'chief investigator' see PARA 92 note 3 ante.

2 The Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 16 does not apply in relation to an opinion given by an ethics committee asked to review an opinion pursuant to reg 16(8), Sch 4 para 2 (see the text to notes 14-17 infra): reg 16(2)(b). For the meaning of 'ethics committee' see PARA 85 note 2 ante.

3 Ie in accordance with *ibid* reg 14: see PARA 92 ante.

4 *Ibid* reg 16(1). As to ethics committee opinions see PARA 93 ante.

5 Where the opinion was given by the gene therapy advisory committee, the chief investigator may, within 14 days of being notified of that opinion give a notice in writing to the committee requiring the committee to review its opinion (*ibid* reg 16(4)(a)), or give a notice in writing to the United Kingdom Ethics Committee Authority stating his wish to appeal against the opinion (reg 16(4)(b)(i)) and setting out his representations with respect to that opinion (reg 16(4)(b)(ii)). Where the gene therapy advisory committee is required by a notice to review its opinion, it must do so within 60 days of receipt of the notice: reg 16(5). On a such review the committee may vary or confirm its opinion and must give notice in writing to the chief investigator of the variation or confirmation: reg 16(6). If the committee confirms its opinion, a chief investigator may within 14

days of being notified of the confirmation give notice in writing to the Authority stating his wish to appeal against the committee's opinion (reg 16(7)(a)) and setting out his representations with respect to that opinion (reg 16(7)(b)). For the meaning of 'the gene therapy advisory committee' see PARA 85 note 2 ante. As to the United Kingdom Ethics Committee Authority see PARA 84 ante.

6 Ibid reg 16(3)(a).

7 Ibid reg 16(3)(b). As to the service of notices see PARA 37 note 8 ante; provision applied by reg 47(1).

8 Ie pursuant to ibid reg 16(3), (7): see the text to notes 5-7 supra.

9 Ibid Sch 4 para 1(1)(a).

10 An appeal panel must consist of a chairman and at least six other members: ibid Sch 4 para 3(1). One of the members must be a person who is not a health care professional (Sch 4 para 3(2)(a)); a person having professional qualifications or experience relating to the conduct of, or use of statistics in, clinical trials, unless those professional qualifications or experience relate only to the ethics of clinical research or medical treatment (Sch 4 para 3(2)(b)); or a person who, although not a health care professional, has been a registered medical practitioner or a person registered in the dentists register under the Dentists Act 1984 (Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, Sch 4 para 3(2)(c)). The Authority may pay to members of an appeal panel such travelling and other allowances as the Authority may determine: Sch 4 para 6. For the meaning of 'health care professional' see PARA 86 note 2 ante. For the meaning of 'clinical trial' see PARA 82 ante. For the meaning of 'registered medical practitioner' see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 4; and as to the register under the Dentists Act 1984 see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 417 et seq.

11 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, Sch 4 para 1(1)(b).

12 Where the opinion was given by the gene therapy advisory committee, the Authority must appoint an appeal panel and refer the opinion to that panel: ibid Sch 4 para 1(4).

13 Ibid Sch 4 para 1(2). Where the Authority refuses to give a direction or appoint a panel, it must send a notice to the chief investigator setting out its reasons for refusal: Sch 4 para 1(3).

14 Ibid Sch 4 para 2(a)(i).

15 Ibid Sch 4 para 2(a)(ii).

16 Ie in accordance with ibid reg 15: see PARA 93 ante.

17 Ibid Sch 4 para 2(b).

18 Ibid Sch 4 para 4(1).

19 Ibid Sch 4 para 4(2)(a).

20 Ibid Sch 4 para 4(2)(b).

21 Ibid Sch 4 para 4(2)(c).

22 Ibid Sch 4 para 4(2)(d). Schedule 4 para 4(2)(d) refers to the matters specified in reg 15(6) (see PARA 93 ante); however, it is submitted that this should be a reference to reg 15(5) (see PARA 93 ante).

23 Ibid Sch 4 para 4(2)(e).

24 Ie pursuant to ibid reg 16(5): see note 5 supra.

25 Ibid Sch 4 para 4(2)(f).

26 Ibid Sch 4 para 4(3).

27 Ibid Sch 4 para 4(4). Schedule 4 para 5 provides that if an appeal panel gives a favourable opinion, the condition specified in reg 11(3)(a) is deemed to have been satisfied. However, there is no reg 11(3)(a); it is submitted that this should be a reference to reg 12(3)(a): see PARA 90 ante.

UPDATE

94 Review and appeal relating to ethics committee opinion

NOTE 3--Now, in accordance with SI 2004/1031 reg 14: reg 16(1) (amended by SI 2006/1928).

NOTE 8--Now, also pursuant to SI 2004/1031 reg 16(4)(b): Sch 4 para 1 (amended by SI 2006/1928).

NOTE 22--Now, SI 2004/1031 Sch 4 para 4(2)(d) refers to the matters specified in reg 15(5): Sch 4 para 4(2)(d) (amended by SI 2006/1928).

TEXT AND NOTE 25--Omit words 'on a review': SI 2004/1031 Sch 4 para 4(2)(f) (amended by SI 2006/1928).

NOTE 27--Now, SI 2004/1031 Sch 4 para 5 refers to the condition specified in reg 12(3) (a): Sch 4 para 5 (amended by SI 2006/1928).

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C. AUTHORISATION FOR CLINICAL TRIALS

95. Request for authorisation to conduct a clinical trial.

A request for authorisation to conduct a clinical trial¹ must be made to the licensing authority² by the sponsor³ of the trial⁴. A request must be in writing and signed⁵ by or on behalf of the sponsor⁶, and be accompanied by the specified particulars and documents⁷ and any fee which may be payable⁸ in connection with that application⁹. The request and any accompanying material must be supplied in the English language¹⁰.

Any person¹¹ who in the course of making a request for authorisation to conduct a clinical trial provides to the licensing authority any relevant information¹² which is false or misleading in a material particular is guilty of an offence¹³.

1 As to the meaning of 'conducting a clinical trial' see PARA 86 note 2 ante. For the meaning of 'clinical trial' see PARA 82 ante.

2 For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1).

3 For the meaning of 'sponsor' see PARA 82 ante.

4 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 17(1).

5 As to references to 'signed' see PARA 92 note 11 ante.

6 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 17(2)(a).

7 Ibid reg 17(2)(b)(i). As to the specified particulars and documents see Sch 3 Pt 2.

8 Ie under the Medicines (Products for Human Use--Fees) Regulations 1995, SI 1995/1116 (as amended): see PARA 11 ante.

9 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 17(2)(b)(ii).

10 Ibid reg 17(3).

11 For the meaning of 'person' see PARA 21 note 7 ante.

12 For the meaning of 'relevant information' see PARA 92 note 15 ante.

13 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 50(1)(b). As to offences generally, defences and penalties see PARAS 123-125 post.

UPDATE

95 Request for authorisation to conduct a clinical trial

TEXT AND NOTES 5-9--No fee need accompany a request where arrangements have been made with the licensing authority for payment of the fee referred to in SI 2004/1031 reg 17(2)(b)(ii) other than at the time of request: reg 17(2A) (added by SI 2006/1928).

NOTE 7--SI 2004/1031 Sch 3 Pt 2 amended: SI 2006/1928.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(5) CLINICAL TRIALS/(iii) Ethics Committee Opinion and Authorisation for Clinical Trials/C. AUTHORISATION FOR CLINICAL TRIALS/96. Authorisation procedure for clinical trials involving general medicinal products.

96. Authorisation procedure for clinical trials involving general medicinal products.

The provisions described below apply to clinical trials¹ involving medicinal products² other than medicinal products for gene therapy³ or medicinal products with special characteristics⁴.

The licensing authority⁵ may, within the period of 30 days from the date of receipt of a valid request for authorisation⁶ of a clinical trial, give written notice to the sponsor⁷ setting out the licensing authority's grounds for not accepting the request⁸, or stating that the licensing authority accepts the request for authorisation⁹, or stating that the licensing authority accepts the request for authorisation subject to the conditions specified in the notice¹⁰. If a notice is given stating that the licensing authority accepts the request for authorisation¹¹, or the licensing authority gives no notice¹², the clinical trial is to be treated as authorised¹³. If a notice is given accepting the request for authorisation subject to conditions, the clinical trial is to be treated as authorised only if the conditions specified in the notice are satisfied¹⁴.

If the sponsor is given a notice not accepting the request or accepting it subject to conditions, he may, within the period of 14 days, or such extended period as the licensing authority may in any particular case allow, from the date on which the notice was received, send an amended request to the licensing authority for further consideration¹⁵. The licensing authority must consider a valid amended request and may, within the period of 60 days from the date on which the original request was received, give a written notice to the sponsor setting out the licensing authority's grounds for not accepting the amended request¹⁶, or stating that the licensing authority accepts the amended request¹⁷, or stating that the licensing authority accepts the amended request subject to the conditions specified in the notice¹⁸. If a valid amended request has been received and a notice is given accepting the amended request¹⁹, or no notice is given²⁰, the clinical trial is to be treated as authorised²¹. If a valid amended request has been received and a notice is given accepting the request subject to conditions, the clinical trial is to be treated as authorised only if the conditions specified in the notice are satisfied²².

If the licensing authority gives written notice to the sponsor of grounds for non-acceptance of a request for authorisation²³ and the sponsor does not submit an amended request²⁴, or the sponsor has submitted an amended request but the licensing authority gives written notice²⁵ to the sponsor of grounds for non-acceptance²⁶, the request is to be treated as rejected and the authority must not consider any further amendments to the request²⁷.

1 For the meaning of 'clinical trial' see PARA 82 ante.

2 For the meaning of 'medicinal product' see PARA 82 note 1 ante.

3 As to applications in respect of clinical trials involving such medicinal products see PARA 97 post.

4 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 18(1). As to applications in respect of clinical trials involving medicinal products with special characteristics see PARA 98 post.

5 For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by *ibid* reg 2(1).

6 'Valid request for authorisation' means a request to the licensing authority for authorisation to conduct a clinical trial which complies with the provisions of *ibid* reg 17 (see PARA 95 ante); and 'valid amended request' must be construed accordingly: reg 11.

7 For the meaning of 'sponsor' see PARA 82 ante. As to the service of notices see PARA 37 note 8 ante; provision applied by *ibid* reg 47(1).

8 *Ibid* reg 18(2)(a). As to appeals against decisions not to accept a request for authorisation or to grant an authorisation subject to conditions see PARA 103 post.

9 *Ibid* reg 18(2)(b).

10 *Ibid* reg 18(2)(c). See also note 8 *supra*.

11 *Ibid* reg 18(3)(a).

12 *Ibid* reg 18(3)(b).

13 *Ibid* reg 18(3).

14 *Ibid* reg 18(4).

15 *Ibid* reg 18(5).

16 *Ibid* reg 18(6)(a).

17 *Ibid* reg 18(6)(b).

18 *Ibid* reg 18(6)(c).

19 *Ibid* reg 18(7)(a).

20 *Ibid* reg 18(7)(b).

21 *Ibid* reg 18(7).

22 *Ibid* reg 18(8).

23 *Ie* in accordance with *ibid* reg 18(2)(a): see the text to note 8 *supra*.

24 *Ibid* reg 18(9)(a).

25 *Ie* in accordance with *ibid* reg 18(6)(a): see the text to note 16 ante.

26 *Ibid* reg 18(9)(b).

27 *Ibid* reg 18(9).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(5) CLINICAL TRIALS/(iii) Ethics Committee Opinion and Authorisation for Clinical Trials/C. AUTHORISATION FOR CLINICAL TRIALS/97. Authorisation procedure for clinical trials involving medicinal products for gene therapy.

97. Authorisation procedure for clinical trials involving medicinal products for gene therapy.

The provisions described below apply to clinical trials¹ involving medicinal products² for gene therapy and somatic cell therapy, including xenogenic cell therapy³, or medicinal products containing genetically modified organisms⁴.

The licensing authority⁵ may, within the period of 30 days from the date of receipt of a valid request for authorisation⁶ of a clinical trial, issue a written authorisation to the sponsor⁷, or give a notice in writing to the sponsor setting out the grounds for not accepting the request⁸. The licensing authority must not authorise a clinical trial involving products for gene therapy if the use of those products in that trial would result in modifications to any subject's⁹ germ line genetic identity¹⁰. If the licensing authority considers that it is appropriate to do so, it may consult the relevant committee¹¹ before deciding whether to authorise a clinical trial¹².

Where a sponsor is given a notice setting out the grounds for not accepting the request, he may, within the period of 30 days, or such extended period as the licensing authority may in any particular case allow, from the date on which the notice was received, send an amended request to the licensing authority for further consideration¹³. The licensing authority must consider a valid amended request¹⁴ and, not later than 90 days¹⁵ from the date on which the original request was received, issue a written authorisation to the sponsor¹⁶ or give a notice in writing to the sponsor setting out the grounds for not accepting the request¹⁷.

A written authorisation issued under these provisions may contain such conditions as the licensing authority considers appropriate¹⁸.

1 For the meaning of 'clinical trial' see PARA 82 ante.

2 For the meaning of 'medicinal product' see PARA 82 note 1 ante.

3 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 19(1)(a).

4 Ibid reg 19(1)(b).

5 For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by ibid reg 2(1).

6 For the meaning of 'valid request for authorisation' see PARA 96 note 6 ante.

7 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 19(2)(a). As to the extension of time where the authority consults the relevant committee see note 12 infra. For the meaning of 'sponsor' see PARA 82 ante. If the clinical trial involves a medicinal product for xenogenic cell therapy, the time limits set out in reg 19(2), (5) (see note 12 infra) and reg 19(7) (see the text to note 15 infra) do not apply and the authority may issue an authorisation or notice under those provisions at any time after receipt of the request: reg 19(9).

8 Ibid reg 19(2)(b). As to the service of notices see PARA 37 note 8 ante; provision applied by reg 47(1).

9 For the meaning of 'subject' see PARA 82 note 1 ante.

10 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 19(3).

11 'The relevant committee' means the Commission on Human Medicines or such other body or committee as the licensing authority may consider appropriate in relation to the application under consideration: ibid reg 19(10) (amended by SI 2005/2754). As to the Commission on Human Medicines see PARA 13 et seq ante.

12 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 19(4). Where the authority consults the relevant committee, the period specified in reg 19(2) (see the text to note 7 *supra*) is extended by a further 90 days: reg 19(5). See also note 7 *supra*.

13 *Ibid* reg 19(6).

14 For the meaning of 'valid amended request' see PARA 96 note 6 *ante*.

15 Or 180 days, in a case where the authority consults the relevant committee (see the text to note 12 *supra*): Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 19(7). See also note 7 *supra*.

16 *Ibid* reg 19(7)(a).

17 *Ibid* reg 19(7)(b).

18 *Ibid* reg 19(8). As to appeals against decisions not to accept a request for authorisation or to grant an authorisation subject to conditions see PARA 103 *post*.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(5) CLINICAL TRIALS/(iii) Ethics Committee Opinion and Authorisation for Clinical Trials/C. AUTHORISATION FOR CLINICAL TRIALS/98. Authorisation procedure for clinical trials involving medicinal products with special characteristics.

98. Authorisation procedure for clinical trials involving medicinal products with special characteristics.

The provisions described below apply to clinical trials¹ involving medicinal products² which do not have a marketing authorisation³ and are of a particular type⁴; or which have a specified active ingredient⁵; or where the licensing authority⁶, within seven days from the date of receipt of a valid request for authorisation⁷ of the trial, issues a notice to the sponsor⁸ specifying that by virtue of the special characteristics of the medicinal product to which the trial relates, written authorisation for that trial is required⁹.

The licensing authority may, within the period of 30 days from the date of receipt of a valid request for authorisation of a clinical trial, issue a written authorisation to the sponsor¹⁰, or give a notice in writing to the sponsor setting out the grounds for not authorising the trial¹¹. Where a sponsor is given a notice setting out the grounds for not authorising the trial, he may, within the period of 14 days, or such extended period as the licensing authority may in any particular case allow, from the date on which the notice was received, send an amended request to the licensing authority for further consideration¹². The licensing authority must consider a valid amended request¹³ and, not later than 60 days from the date on which the original request was received, issue a written authorisation to the sponsor¹⁴, or give a notice in writing to the sponsor setting out the grounds for not accepting the request¹⁵.

A written authorisation issued under these provisions may contain such conditions as the licensing authority considers appropriate¹⁶.

1 For the meaning of 'clinical trial' see PARA 82 ante.

2 For the meaning of 'medicinal product' see PARA 82 note 1 ante.

3 For the meaning of 'marketing authorisation' see PARA 82 note 1 ante.

4 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 20(1)(a)(i). The medicinal products must be of a type referred to in EC Council Regulation 2309/93 (OJ L214, 24.8.1993, p 1) Annex Pt A.

5 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 20(1)(a)(ii). This provision refers to medicinal products which have an active ingredient:

61 (1) that is a biological product of human or animal origin (reg 20(1)(a)(ii)(aa));

62 (2) containing biological components of human or animal origin (reg 20(1)(a)(ii)(bb)); or

63 (3) the manufacturing of which requires such components (reg 20(1)(a)(ii)(cc)),

other than products falling within reg 19 (see PARA 97 ante) (reg 20(1)(a)(ii)).

6 For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by ibid reg 2(1).

7 For the meaning of 'valid request for authorisation' see PARA 96 note 6 ante.

8 For the meaning of 'sponsor' see PARA 82 ante.

9 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 20(1)(b).

10 Ibid reg 20(2)(a).

11 Ibid reg 20(2)(b). As to the service of notices see PARA 37 note 8 ante; provision applied by reg 47(1). As to appeals against decisions not to accept a request for authorisation or to grant an authorisation subject to conditions see PARA 103 post.

12 Ibid reg 20(3).

13 For the meaning of 'valid amended request' see PARA 96 note 6 ante.

14 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 20(4)(a).

15 Ibid reg 20(4)(b).

16 Ibid reg 20(5). See also note 11 supra.

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99. Clinical trials conducted in third countries.

If the licensing authority¹ receives a valid request for authorisation² relating to a clinical trial³ which is or is to be conducted⁴ in a third country⁵ as well as the United Kingdom⁶, the licensing authority may, if it thinks fit, require the production by the sponsor⁷ of any one or more of the following:

- 89 (1) an undertaking, given by the sponsor, to permit its premises in that country to be inspected by or on behalf of the licensing authority for the purpose of establishing whether the conditions and principles of good clinical practice⁸ are satisfied or adhered to in relation to that trial⁹; or
- 90 (2) an undertaking, given by the owner or occupier of any premises in that country at which the clinical trial is or is to be conducted, to permit those premises to be inspected by or on behalf of the licensing authority for the purpose of establishing whether the conditions and principles of good clinical practice are satisfied or adhered to in relation to that trial¹⁰.

If a sponsor fails to produce an undertaking required by the licensing authority, that failure constitutes¹¹ a ground for not accepting the request for authorisation¹².

1 For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1).

2 For the meaning of 'valid request for authorisation' see PARA 96 note 6 ante.

3 For the meaning of 'clinical trial' see PARA 82 ante.

4 As to the meaning of 'conducting a clinical trial' see PARA 86 note 2 ante.

5 'Third country' means a country or territory outside the European Economic Area: Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1). For the meaning of 'European Economic Area' see PARA 82 note 1 ante.

6 For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

7 For the meaning of 'sponsor' see PARA 82 ante.

8 For the meaning of 'the conditions and principles of good clinical practice' see PARA 104 note 5 post.

9 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 21(1)(a).

10 Ibid reg 21(1)(b).

11 Ie for the purposes of ibid regs 18-20: see PARAS 96-98 ante.

12 Ibid reg 21(2).

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100. Amendments to clinical trial authorisation by the licensing authority.

Subject to the provisions relating to urgent safety measures¹, an amendment to a clinical trial authorisation² may be made by the licensing authority³, or by the sponsor⁴.

The licensing authority may make amendments to a clinical trial authorisation if it appears to the authority to be necessary to ensure the safety or scientific validity of the clinical trial⁵, or that the conditions and principles of good clinical practice⁶ are satisfied or adhered to in relation to the clinical trial⁷. Where the licensing authority proposes to make an amendment, it must, at least 14 days before the date on which it is proposed the amendment should take effect, serve a notice on the sponsor stating its proposal and the reasons for it⁸. If, within 14 days of the date such a notice is served, the sponsor makes representations in writing to the licensing authority, the authority must take those representations into account before deciding whether to make the amendment⁹, and may delay the date the proposed amendment is to take effect in order to allow time for it to consider those representations¹⁰.

1 Ie the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 30: see PARA 106 post.

2 'Amendment to the clinical trial authorisation' means an amendment to: (1) the terms of the request for authorisation to conduct that trial or the application for an ethics committee opinion in relation to that trial; (2) the protocol for that trial; or (3) the other particulars or documents accompanying that request for authorisation or application for ethics committee approval: *ibid* reg 11. For the meaning of 'clinical trial' see PARA 82 ante. As to requests for clinical trial authorisations see PARA 95 ante; and as to authorisations see PARAS 96-99 ante. As to applications for ethics committee opinions see PARA 92 ante. For the meaning of 'protocol' see PARA 82 note 2 ante.

3 *Ibid* reg 22(a). For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by reg 2(1).

4 *Ibid* reg 22(b). As to such applications see regs 24-25; and PARAS 101-102 post. For the meaning of 'sponsor' see PARA 82 ante.

5 *Ibid* reg 23(1)(a). As to appeals against amendments see reg 26; and PARA 103 post.

6 For the meaning of 'the conditions and principles of good clinical practice' see PARA 104 note 5 post.

7 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 23(1)(b).

8 *Ibid* reg 23(2). As to the service of notices see PARA 37 note 8 ante; provision applied by reg 47(1).

9 *Ibid* reg 23(3)(a).

10 *Ibid* reg 23(3)(b).

UPDATE

100 Amendments to clinical trial authorisation by the licensing authority

NOTES 5, 7--SI 2004/1031 reg 23(1) amended: SI 2006/1928.

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101. Amendments to clinical trial authorisation by the sponsor.

Subject to the provisions relating to urgent safety measures¹, a sponsor² may make an amendment to a clinical trial authorisation³, other than a substantial amendment⁴, at any time⁵. A sponsor must keep records of the amendments made⁶ and send those records, or copies of such records, to the licensing authority⁷ where the authority sends him a notice in writing requiring him to provide those records, or copies of such records⁸.

If the sponsor proposes to make a substantial amendment to a clinical trial authorisation which consists of, or includes, an amendment to the terms of the request for authorisation of the clinical trial⁹, or the particulars or documents that accompanied that request¹⁰, he must send a valid notice of amendment¹¹ to the licensing authority¹². The licensing authority may, within the period of 35 days from the date of receipt of a valid notice of amendment, give written notice to the sponsor setting out the licensing authority's grounds for not accepting the proposed amendment¹³, or stating that the licensing authority accepts the application for amendment, subject to any conditions which may be specified in the notice¹⁴. If the sponsor has sent a notice¹⁵, he may make the amendment only if the licensing authority have given him a notice stating that it accepts the application for amendment¹⁶, or no notice has been given by the licensing authority¹⁷.

If the sponsor proposes to make a substantial amendment to a clinical trial authorisation which consists of, or includes, an amendment to the terms of the application for an ethics committee opinion in relation to the clinical trial¹⁸, or the particulars or documents that accompanied that application¹⁹, he must send a valid notice of amendment to the relevant ethics committee²⁰. A relevant ethics committee must, within the period of 35 days from the date of receipt of a valid notice of amendment, give an opinion to the sponsor²¹. If the sponsor has sent a notice²² to the relevant ethics committee, he may make the amendment only if the relevant ethics committee has given a favourable opinion²³.

1 Ie the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 30: see PARA 106 post.

2 For the meaning of 'sponsor' see PARA 82 ante.

3 See the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 22(b). For the meaning of 'amendment to the clinical trial authorisation' see PARA 100 note 2 ante. As to clinical trial authorisations see PARAS 95-99 ante. For the meaning of 'clinical trial' see PARA 82 ante. As to infringement notices see PARA 122 post.

4 'Substantial amendment to the clinical trial authorisation' means an amendment to the clinical trial authorisation which is likely to affect to a significant degree: (1) the safety or physical or mental integrity of the subjects of the trial; (2) the scientific value of the trial; (3) the conduct or management of the trial; or (4) the quality or safety of any investigational medicinal product used in the trial: *ibid* reg 11. For the meanings of 'subject' and 'investigational medicinal product' see PARA 82 note 1 ante.

5 *Ibid* reg 24(1).

6 *Ibid* reg 24(2)(a).

7 For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by *ibid* reg 2(1).

8 *Ibid* reg 24(2)(b). As to the service of notices see PARA 37 note 8 ante; provision applied by reg 47(1).

9 Ibid reg 24(3)(a).

10 Ibid reg 24(3)(b).

11 'Valid notice of amendment' means a notice that is in writing and accompanied by the specified particulars and any fee which may be payable in connection with that notice under the Medicines (Products for Human Use--Fees) Regulations 1995, SI 1995/1116 (as amended) (see PARA 11 ante); Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 24(10). As to the specified particulars see Sch 3 Pt 3.

12 Ibid reg 24(3). The sponsor must send such notice whether or not he is also required to send a notice in accordance with reg 24(4) (see the text to notes 18-20 infra): reg 24(3).

13 Ibid reg 24(5)(a). As to modifying or adapting rejected proposals for amendment see PARA 102 post. As to appeals against rejected proposals see PARA 103 post.

14 Ibid reg 24(5)(b).

15 Ie in accordance with ibid reg 24(3): see the text to notes 9-12 supra.

16 Ibid reg 24(7)(a). If the sponsor has been given a notice stating that the licensing authority accepts the application for amendment, he may make the amendment subject to the conditions, if any, specified in the notice: reg 24(8).

17 Ibid reg 24(7)(b).

18 Ibid reg 24(4)(a). As to applications for ethics committee opinions see PARA 92 ante.

19 Ibid reg 24(4)(b).

20 Ibid reg 24(4). The sponsor must send such a notice whether or not he is also required to send a notice in accordance with reg 24(3) (see the text to notes 9-12 supra): reg 24(4). 'Relevant ethics committee', in relation to a clinical trial, means: (1) in a case where an ethics committee has given a favourable opinion in relation to that trial and Sch 2 para 13 (see PARA 85 ante) applies, the ethics committee which is the relevant ethics committee for that trial by virtue of Sch 2 para 13(5); (2) in a case where an ethics committee has given an unfavourable opinion in relation to that trial but a favourable opinion has been given by an appeal panel in accordance with Sch 4 para 4(4) (see PARA 94 ante), that committee; or (3) in any other case, the ethics committee which has given a favourable opinion in relation to that trial in accordance with reg 15 (see PARA 93 ante): reg 2(1).

21 Ibid reg 24(6). As to modifying or adapting rejected proposals for amendment see PARA 102 post.

22 Ie in accordance with ibid reg 24(4): see the text to notes 18-20 supra.

23 Ibid reg 24(9).

UPDATE

101 Amendments to clinical trial authorisation by the sponsor

NOTE 11--Definition of 'valid notice of amendment' in SI 2004/1031 reg 24(10) amended: SI 2006/1928. SI 2004/1031 Sch 3 Pt 3 amended: SI 2006/1928.

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102. Modifying or adapting rejected proposals for amendment.

If the ethics committee¹ opinion on a proposed amendment² to the protocol³ is not favourable⁴, or the sponsor⁵ has been notified by the licensing authority⁶ of any grounds for non-acceptance of a proposed amendment to the protocol⁷, and it is possible to modify or adapt the proposed amendment in order to meet the concerns of the ethics committee or the licensing authority as set out in the opinion or, as the case may be, the grounds for non-acceptance, the sponsor may amend the protocol accordingly⁸. If a sponsor proposes to so amend the protocol, he must, at least 14 days before the amendment is to be made, give a notice in writing to the licensing authority and the relevant ethics committee⁹. The licensing authority may, within the period of 14 days from the date of receipt of such a notice, give written notice to the sponsor setting out the licensing authority's further grounds for not accepting the modified or adapted amendment¹⁰; and the relevant ethics committee may, within the period of 14 days from the date of receipt of such a notice, give a written notice to the sponsor stating that its opinion of the modified or adapted amendment is unfavourable¹¹. If the sponsor receives such a written notice from the licensing authority or the relevant ethics committee, he may not make the amendment¹²; and if he receives no such notice he may make the modified or adapted amendment¹³.

1 For the meaning of 'ethics committee' see PARA 85 note 2 ante.

2 As to ethics committee opinions on proposed amendments see PARA 101 ante.

3 For the meaning of 'protocol' see PARA 82 note 2 ante.

4 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 25(1)(a).

5 For the meaning of 'sponsor' see PARA 82 ante.

6 As to such notifications see PARA 101 ante. For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1).

7 Ibid reg 25(1)(b).

8 Ibid reg 25(1).

9 Ibid reg 25(2). For the meaning of 'relevant ethics committee' see PARA 101 note 20 ante. As to the service of notices see PARA 37 note 8 ante; provision applied by reg 47(1).

10 Ibid reg 25(3). As to appeals against such decisions see PARA 103 post.

11 Ibid reg 25(4).

12 Ibid reg 25(5)(a).

13 Ibid reg 25(5)(b).

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103. Reference to the appropriate committee or the Commission on Human Medicines.

If:

- 91 (1) a sponsor¹ has been notified by the licensing authority² that there are grounds for not accepting a request for authorisation³, or the trial is authorised⁴ subject to specified conditions⁵;
- 92 (2) the licensing authority has amended⁶ a clinical trial authorisation⁷; or
- 93 (3) the sponsor has been notified⁸ by the licensing authority that the authority does not accept a proposed, modified or adapted amendment to the clinical trial authorisation⁹, or the authority accepts such an amendment subject to conditions¹⁰,

the sponsor may, within 28 days, or such extended period as the licensing authority may in any particular case allow, of the notice being given, give notice¹¹ in writing to the licensing authority of his wish to make written or oral representations to the appropriate committee¹².

Where the licensing authority is notified¹³ of the wish of a sponsor or investigator¹⁴ to make representations, the authority must inform the appropriate committee and the committee must give the sponsor or investigator an opportunity to make such representations¹⁵. The sponsor or investigator must provide the appropriate committee with his written representations or a written summary of the oral representations he intends to make¹⁶ and any documents on which he wishes to rely in support of those representations¹⁷, before the end of the period of six months beginning with the date of the notice or within such shorter period as the licensing authority may specify in its notification¹⁸. If the sponsor or investigator gave notice of his wish to make oral representations, the appropriate committee must, after receiving a written summary and any other documents, arrange for the sponsor or investigator to make such representations at a hearing before the committee¹⁹. The appropriate committee must take into account such representations as are made²⁰ and report its findings and advice to the licensing authority, together with the reasons for its advice²¹.

In the case of a decision not to accept a request for authorisation to conduct a clinical trial or an amendment to the clinical trial authorisation, the licensing authority must, after considering the report of the appropriate committee confirm that it has grounds for not accepting the request or amendment²², or accept the request for authorisation or amendment to the clinical trial authorisation subject to such conditions as the licensing authority may consider appropriate²³. In the case of a decision to impose a condition following a request for authorisation to conduct a clinical trial or a notice of amendment to a clinical trial authorisation, the licensing authority must, after considering the report of the appropriate committee, confirm its decision²⁴ or remove or alter the condition in question²⁵.

1 For the meaning of 'sponsor' see PARA 82 ante.

2 For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1).

3 Ibid reg 26(1)(a)(i). As to requests for authorisation see PARA 95 ante.

- 4 le in accordance with ibid reg 18(2), (6) (see PARA 96 ante), reg 19(8) (see PARA 97 ante), reg 20(5) (see PARA 98 ante).
- 5 Ibid reg 26(1)(a)(ii).
- 6 le under ibid reg 23: see PARA 100 ante.
- 7 Ibid reg 26(1)(b). For the meaning of 'clinical trial' see PARA 82 ante.
- 8 le in accordance with ibid reg 24(5) (see PARA 101 ante) or reg 25(3) (see PARA 102 ante).
- 9 Ibid reg 26(1)(c)(i) (amended by SI 2005/2754).
- 10 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 26(1)(c)(ii).
- 11 As to the service of notices see PARA 37 note 8 ante; provision applied by ibid reg 47(1).
- 12 Ibid reg 26(1) (amended by SI 2005/2754). 'Appropriate committee', for the purposes of any provision of the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031 (as amended) under which a function falls to be performed, means: (1) in a case where a committee has been established under the Medicines Act 1968 s 4 (as amended) (see PARA 15 ante) for purposes which consist of or include any of those specified in s 4(3), and the authority performing that function considers it to be the appropriate committee in the circumstances, that committee; and (2) in any other case, the Commission on Human Medicines: Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1) (definition substituted by SI 2005/2754). As to the Commission on Human Medicines see PARA 13 et seq ante.
- 13 le in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 26(1) (as amended) (see the text and notes 1-12 supra) or reg 31(7) (as amended) (see PARA 107 post).
- 14 For the meaning of 'investigator' see PARA 86 note 2 ante.
- 15 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, regs 26(2), 31(8), Sch 5 para 1(1) (regs 26(2), 31(8) amended, and Sch 5 substituted, by SI 2005/2754).
- 16 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, Sch 5 para 1(2)(a) (as substituted: see note 15 supra).
- 17 Ibid Sch 5 para 1(2)(b) (as substituted: see note 15 supra).
- 18 Ibid Sch 5 para 1(2) (as substituted: see note 15 supra). If the sponsor or investigator so requests, the appropriate committee may extend the time limit up to a maximum period of 12 months beginning with the date of the notice: Sch 5 para 1(3) (as so substituted). The sponsor or investigator may not submit any additional written representations or documents once the time limit or time limit as extended has expired except with the permission of the appropriate committee: Sch 5 para 1(4) (as so substituted).
- 19 Ibid Sch 5 para 1(5) (as substituted: see note 15 supra).
- 20 Ibid Sch 5 para 1(6)(a) (as substituted: see note 15 supra).
- 21 Ibid Sch 5 para 1(6)(b) (as substituted: see note 15 supra).
- 22 Ibid Sch 5 para 2(1)(a) (as substituted: see note 15 supra).
- 23 Ibid Sch 5 para 2(1)(b) (as substituted: see note 15 supra).
- 24 Ibid Sch 5 para 2(2)(a) (as substituted: see note 15 supra).
- 25 Ibid Sch 5 para 2(2)(b) (as substituted: see note 15 supra).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(5) CLINICAL TRIALS/(iv) Conduct of Clinical Trials/104. Good clinical practice and protection of clinical trial subjects.

(iv) Conduct of Clinical Trials

104. Good clinical practice and protection of clinical trial subjects.

No person¹ may conduct a clinical trial², or perform the functions of the sponsor³ of a clinical trial⁴, otherwise than in accordance with the conditions and principles of good clinical practice⁵. The sponsor of a clinical trial must put and keep in place arrangements for the purpose of ensuring that with regard to that trial the conditions and principles of good clinical practice are satisfied or adhered to⁶. The sponsor of a clinical trial must ensure that the investigational medicinal products⁷ used in the trial⁸, and any devices used for the administration of such products⁹, are made available to the subjects¹⁰ of the trial free of charge¹¹.

Any person who contravenes these provisions¹² is guilty of an offence¹³.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 28(1)(a). As to the meaning of 'conducting a clinical trial' see PARA 86 note 2 ante. For the meaning of 'clinical trial' see PARA 82 ante.

3 For the meaning of 'sponsor' see PARA 82 ante.

4 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 28(1)(b). This restriction applies whether that person is the sponsor or is acting under arrangements made with that sponsor: reg 28(1)(b).

5 Ibid reg 28(1). 'Conditions and principles of good clinical practice' means the conditions and principles specified in the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031: reg 2(1). As to such conditions and principles see Sch 1. As to infringement notices see PARA 122 post.

6 Ibid reg 28(2). If a clinical trial is conducted at more than one trial site, and the request for authorisation to conduct that trial specifies that in relation to one or more trial sites the duties of the sponsor under reg 28(2), (3) (see the text to notes 7-11 infra) are to be performed by a person other than the sponsor, those duties must, in relation to that site or those sites, be performed by the person so specified: reg 28(5).

7 For the meaning of 'investigational medicinal product' see PARA 82 note 1 ante.

8 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 28(3)(a).

9 Ibid reg 28(3)(b).

10 For the meaning of 'subject' see PARA 82 note 1 ante.

11 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 28(3). This restriction does not apply in relation to any charge payable by a subject under regulations made under the National Health Service Act 1977, the National Health Service (Scotland) Act 1978, or the Health and Personal Social Services (Northern Ireland) Order 1972, SI 1972/1265 (NI 14), in respect of any medicinal products or devices provided in pursuance of those Acts or that order: Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 28(4). See also note 6 supra.

12 Ie the provisions of ibid reg 28(1)-(3).

13 Ibid reg 49(1)(d). As to offences generally, defences and penalties see PARAS 123-125 post.

UPDATE

104-111 Conduct of Clinical Trials

The sponsor is required to notify the licensing authority of serious breaches, and is required to keep a trial master file for a clinical trial: see the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, regs 29A, 31A; and PARAS 105A, 107A.

104 Good clinical practice and protection of clinical trial subjects

NOTE 5--SI 2004/1031 Sch 1 amended: SI 2006/1928, SI 2006/2984, SI 2008/941.

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105. Conduct of trial in accordance with clinical trial authorisation.

Subject to the provisions relating to urgent safety measures¹, no person² may conduct a clinical trial³ otherwise than in accordance with: (1) the protocol⁴ relating to that trial, as amended⁵ from time to time⁶; (2) the terms, as amended from time to time⁷, of the request for authorisation to conduct that trial⁸, the application for an ethics committee⁹ opinion in relation to that trial¹⁰, and any particulars or documents, other than the protocol, accompanying that request or that application¹¹; (3) any conditions imposed by the licensing authority¹² on an authorisation¹³.

Any person who contravenes these provisions is guilty of an offence¹⁴.

1 Ie the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 30: see PARA 106 post.

2 For the meaning of 'person' see PARA 21 note 7 ante.

3 As to the meaning of 'conducting a clinical trial' see PARA 86 note 2 ante. For the meaning of 'clinical trial' see PARA 82 ante. As to infringement notices see PARA 122 post.

4 For the meaning of 'protocol' see PARA 82 note 2 ante.

5 Ie in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, regs 22-25: see PARAS 100-102 ante.

6 Ibid reg 29(a).

7 Ie in accordance with ibid regs 22-25: see PARAS 100-102 ante.

8 Ibid reg 29(b)(i). As to requests for authorisation see PARA 95 ante.

9 For the meaning of 'ethics committee' see PARA 85 note 2 ante.

10 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 29(b)(ii). As to applications for ethics committee opinions see PARA 92 ante.

11 Ibid reg 29(b)(iii).

12 Ie under ibid reg 18(2), (6) (see PARA 96 ante), reg 19(8) (see PARA 97 ante), reg 20(5) (see PARA 98 ante), reg 24(4) (see PARA 101 ante), reg 26, Sch 5 (see PARA 103 ante). For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by reg 2(1).

13 Ibid reg 29(c).

14 Ibid reg 49(1)(e). As to offences generally, defences and penalties see PARAS 123-125 post.

UPDATE

104-111 Conduct of Clinical Trials

The sponsor is required to notify the licensing authority of serious breaches, and is required to keep a trial master file for a clinical trial: see the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, regs 29A, 31A; and PARAS 105A, 107A.

105 Conduct of trial in accordance with clinical trial authorisation

NOTE 12--For 'reg 24(4)' read 'reg 24(5)': SI 2004/1031 reg 29(c) (amended by SI 2006/1928).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(5) CLINICAL TRIALS/(iv) Conduct of Clinical Trials/105A. Notification of serious breaches.

105A. Notification of serious breaches.

The sponsor¹ of a clinical trial² must notify the licensing authority³ in writing of any serious breach⁴ of the conditions and principles of good clinical practice in connection with that trial, or any serious breach of the protocol⁵ relating to that trial within seven days of becoming aware of that breach⁶. Breach of these provisions is an offence⁷.

1 For the meaning of 'sponsor' see PARA 82.

2 For the meaning of 'clinical trial' see PARA 82.

3 For the meaning of 'the licensing authority' see PARA 43 NOTE 8.

4 A 'serious breach' is a breach which is likely to effect to a significant degree the safety or physical or mental integrity of the subjects of the trial or the scientific value of the trial: Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 29A (reg 29A added by SI 2006/1928). For the meaning of 'subject' see PARA 82 NOTE 1.

5 Ie the protocol as amended from time to time in accordance with SI 2004/1031 regs 22-25 (see PARAS 99-102). For the meaning of 'protocol' see PARA 82.

6 Ibid reg 29A(1).

7 Ibid reg 49(1)(ee) (added by SI 2006/1928). As to offences generally, defences and penalties see PARAS 123-125.

UPDATE

104-111 Conduct of Clinical Trials

The sponsor is required to notify the licensing authority of serious breaches, and is required to keep a trial master file for a clinical trial: see the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, regs 29A, 31A; and PARAS 105A, 107A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(5) CLINICAL TRIALS/(iv) Conduct of Clinical Trials/106. Urgent safety measures.

106. Urgent safety measures.

The sponsor¹ and investigator² may take appropriate urgent safety measures in order to protect the subjects³ of a clinical trial⁴ against any immediate hazard to their health or safety⁵. If such measures are taken, the sponsor must immediately, and in any event no later than three days from the date the measures are taken, give written notice to the licensing authority⁶ and the relevant ethics committee⁷ of the measures taken and the circumstances giving rise to those measures⁸. Any person⁹ who contravenes this provision relating to the giving of notice¹⁰ is guilty of an offence¹¹.

1 For the meaning of 'sponsor' see PARA 82 ante.

2 For the meaning of 'investigator' see PARA 86 note 2 ante.

3 For the meaning of 'subject' see PARA 82 note 1 ante.

4 For the meaning of 'clinical trial' see PARA 82 ante.

5 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 30(1).

6 For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by ibid reg 2(1). As to the service of notices see PARA 37 note 8 ante; provision applied by reg 47(1).

7 For the meaning of 'relevant ethics committee' see PARA 101 note 20 ante.

8 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 30(2). As to infringement notices see PARA 122 post.

9 For the meaning of 'person' see PARA 21 note 7 ante.

10 Ie the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 30(2): see the text to note 6-8 supra.

11 Ibid reg 49(1)(f). As to offences generally, defences and penalties see PARAS 123-125 post.

UPDATE

104-111 Conduct of Clinical Trials

The sponsor is required to notify the licensing authority of serious breaches, and is required to keep a trial master file for a clinical trial: see the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, regs 29A, 31A; and PARAS 105A, 107A.

106 Urgent safety measures

TEXT AND NOTES 6-8--SI 2004/1031 reg 30(2), (3) substituted for reg 30(2): SI 2009/1164.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(5) CLINICAL TRIALS/(iv) Conduct of Clinical Trials/107. Suspension or termination of clinical trial.

107. Suspension or termination of clinical trial.

If, in relation to a clinical trial¹: (1) the licensing authority² has objective grounds for considering that any condition, restriction or limitation which applies to the conduct of the trial³ and is set out in the request for authorisation⁴ or the particulars or documents accompanying that request⁵, or any condition imposed⁶ by the licensing authority⁷, is no longer satisfied, either generally or at a particular trial site⁸; or (2) the licensing authority has information raising doubts about the safety or scientific validity of the trial, or the conduct of the trial at a particular trial site⁹, then the licensing authority may, by a notice¹⁰, require that the trial, or the conduct of the trial at a particular trial site, be suspended or terminated¹¹. Except where it appears to the licensing authority that there is an imminent risk to the health or safety of any of the subjects¹² of the clinical trial¹³, at least one week before issuing such a notice the licensing authority must, by a notice in writing to the sponsor or the investigator, inform him that the authority is minded to issue a notice suspending or terminating the trial, or the conduct of a trial at a particular site, and of the reasons why it is so minded¹⁴, and advise him that he may, within one week of the date of the notice, furnish the authority with written representations as to whether the trial, or the conduct of the trial at the particular site, should be so suspended or terminated¹⁵.

A person¹⁶ on whom a notice has been served may, within 28 days, or such extended period as the licensing authority may in any particular case allow, of the notice being given, give notice of his wish to make written or oral representations to the appropriate committee¹⁷. The licensing authority must, after considering the report of the appropriate committee, confirm or revoke the notice¹⁸, and give notice to the sponsor or investigator of its decision¹⁹. Where the notice of suspension or termination is referred to an appropriate committee, it remains in force unless revoked in accordance with the provisions relating to such referral²⁰.

Any person who fails to comply with a notice of suspension or termination served on him, unless that notice has been withdrawn or revoked by the licensing authority, is guilty of an offence²¹.

1 For the meaning of 'clinical trial' see PARA 82 ante.

2 For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1).

3 As to the meaning of 'conducting a clinical trial' see PARA 86 note 2 ante.

4 As to requests for authorisation see PARA 95 ante.

5 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 31(1)(a)(i).

6 *Ie* under *ibid* reg 18(2), (6) (see PARA 96 ante), reg 19(8) (see PARA 97 ante), reg 20(5) (see PARA 98 ante), reg 24(4) (see PARA 101 ante), reg 26, Sch 5 (see PARA 103 ante).

7 *Ibid* reg 31(1)(a)(ii).

8 *Ibid* reg 31(1)(a). For the meaning of 'trial site' see PARA 86 note 2 ante.

9 *Ibid* reg 31(1)(b).

10 A notice must be served: (1) in a case where the suspension or termination applies to the trial generally, on the sponsor (*ibid* reg 31(2)(a)(i)) or the investigator at each trial site (reg 31(2)(a)(ii)); (2) in a case where

the suspension or termination applies to the conduct of a trial at a particular trial site, on the sponsor (reg 31(2)(b)(i)) or the investigator at that trial site (reg 31(2)(b)(ii)). For the meaning of 'sponsor' see PARA 82 ante. For the meaning of 'investigator' see PARA 86 note 2 ante. The notice must specify whether the notice applies to the trial generally or to one or more of the trial sites (reg 31(3)(a)); whether the notice requires suspension or termination of the trial (reg 31(3)(b)); if the notice requires suspension of the trial, whether the suspension applies until further notice from the licensing authority or for such period as may be specified in the notice (reg 31(3)(c)(i)), and any conditions which are to be satisfied before the trial or, as the case may be, the conduct of the trial at a particular site, may be recommenced (reg 31(3)(c)(ii)); and whether suspension or termination is to take effect immediately on receipt of the notice or on such date as may be specified in the notice (reg 31(3)(d)). As to the service of notices see PARA 37 note 8 ante; provision applied by reg 47(1).

11 Ibid reg 31(1). If the licensing authority issues such a notice, it must forthwith inform: (1) where the notice has not been served on the sponsor, the sponsor (reg 31(4)(a)); (2) competent authorities of each EEA state, other than the United Kingdom (reg 31(4)(b)); (3) the relevant ethics committee (reg 31(4)(c)); (4) the European Medicines Agency (reg 31(4)(d)); and (5) the European Commission (reg 31(4)(e)). For the meaning of 'EEA state' see PARA 82 note 1 ante. For the meaning of 'United Kingdom' see PARA 7 note 3 ante. For the meaning of 'relevant ethics committee' see PARA 101 note 20 ante. 'The European Medicines Agency' means the European Medicines Agency established by EC Parliament and Council Regulation 726/2004 (OJ L137, 30.4.2004, p 1) laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency: Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1) (definition substituted by SI 2004/3224).

12 For the meaning of 'subject' see PARA 82 note 1 ante.

13 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 31(6).

14 Ibid reg 31(5)(a).

15 Ibid reg 31(5)(b).

16 For the meaning of 'person' see PARA 21 note 7 ante.

17 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 31(7) (reg 31(7)-(9) amended by SI 2004/2754). For the meaning of 'the appropriate committee' see PARA 103 note 12 ante.

The Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, Sch 5 (as substituted) has effect to regulate the procedure for reference to the appropriate committee: reg 31(8) (as so amended). See the text and notes 18-19 infra; and PARA 103 ante.

18 Ibid Sch 5 para 2(3) (Sch 5 substituted by SI 2005/2754).

19 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, Sch 5 para 2(4)(b) (as substituted: see note 18 supra). The notice must also give details of the findings and advice of the appropriate committee and the reasons for it: Sch 5 para 2(4)(a) (as so substituted). If a sponsor or investigator to whom such a notice is given is dissatisfied, he may within 28 days of the notice being given, or such longer period as the licensing authority may in any particular case allow, notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority with respect to the decision (Sch 5 para 3(1)(a) (as so substituted)), or make representations in writing to the licensing authority with respect to the decision referred to in the notice (Sch 5 para 3(1)(b) (as so substituted)). However, Sch 5 para 3(1)(a) (as substituted) does not apply where the sponsor or investigator had not made any representations in accordance with Sch 5 para 1(2)-(5) (as substituted) (see PARA 103 ante) (Sch 5 para 3(2)(a) (as so substituted)) and the decision of the licensing authority was in accordance with the advice of the appropriate committee (Sch 5 para 3(2)(b) (as so substituted)). If the sponsor or investigator makes written representations in accordance with Sch 5 para 3(2)(b) (as substituted), the licensing authority must take those representations into account before deciding whether to confirm or alter its decision: Sch 5 para 3(3) (as so substituted). As to the procedure in cases to be heard before a person appointed after the giving of a notice under Sch 5 para 3(1)(a) (as substituted) see Sch 5 para 4 (as so substituted).

20 Ibid reg 31(9) (as amended: see note 17 supra).

21 Ibid reg 49(3). As to offences generally, defences and penalties see PARAS 123-125 post.

UPDATE

104-111 Conduct of Clinical Trials

The sponsor is required to notify the licensing authority of serious breaches, and is required to keep a trial master file for a clinical trial: see the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, regs 29A, 31A; and PARAS 105A, 107A.

107 Suspension or termination of clinical trial

NOTE 6--For 'reg 24(4)' read 'reg 24(5)': SI 2004/1031 reg 31(1)(a)(i) (amended by SI 2006/1928).

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107A. Trial master file.

The sponsor¹ must keep a trial master file for a clinical trial², and must ensure that it is readily available at all reasonable times for inspection by the licensing authority³ or by any person appointed by the sponsor to audit the arrangements for the trial⁴. The master file must at all times contain the essential documents⁵ relating to that clinical trial⁶, which are to contain information specific to each phase of the trial⁷. The sponsor is also required to ensure the traceability of any alteration to a document contained, or which has been contained, in the trial master file⁸. It is an offence to contravene these provisions⁹.

1 For the meaning of 'sponsor' see PARA 82.

2 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 31A(1) (reg 31A added by SI 2006/1928). For the meaning of 'clinical trial' see PARA 82. The sponsor must appoint named individuals in his organisation to be responsible for archiving the documents which are, or have been, contained in the trial master file and, subject to SI 2004/1031 reg 31A(2), access to those documents must be restricted to those appointed individuals: reg 31A(9). For the purposes of reg 31A, an individual is an individual in the sponsor's organisation where (1) he is employed or engaged by the sponsor; (2) he is acting under arrangements made with the sponsor for the purposes of managing or conducting the clinical trial; (3) where the sponsor is an individual, he is the sponsor; or (4) where the sponsor is a body of persons, he is a member of the body or employed or engaged by such a member: reg 31A(10).

3 For the meaning of 'the licensing authority' see PARA 43 NOTE 8.

4 SI 2004/1031 reg 31A(2).

5 The essential documents relating to a clinical trial are those which enable both the conduct of the clinical trial and the quality of the data produced to be evaluated and show whether the trial is, or has been, conducted in accordance with the applicable requirements of EC Parliament and Council Directive 2001/83, EC Parliament and Council Directive 2001/20, EC Commission Directive 2005/28 and EC Commission Directive 2003/94: SI 2004/1031 reg 31A(4).

6 Ibid reg 31A(3).

7 Ibid reg 31A(5).

8 Ibid reg 31A(6). The sponsor and the chief investigator must ensure that the documents contained, or which have been contained, in the trial master file are retained for at least five years after the conclusion of the trial and that during that period are readily available to the licensing authority on request, and are complete and legible: reg 31A(7) (as so added). For the meaning of 'chief investigator' see PARA 92 NOTE 3. The sponsor and chief investigator must ensure that the medical files of trial subjects are retained for at least five years after the conclusion of the trial: reg 31A(8). For the meaning of 'subject' see PARA 82 NOTE 1. If there is transfer of ownership of data or documents connected with the clinical trial, the sponsor must record the transfer and the new owner is to be responsible for data retention and archiving in accordance with reg 31A(2), (7) and (8): reg 31A(9).

9 Ibid reg 49(1)(ff) (added by SI 2006/1928). As to offences generally, defences and penalties see PARAS 123-125.

UPDATE

104-111 Conduct of Clinical Trials

The sponsor is required to notify the licensing authority of serious breaches, and is required to keep a trial master file for a clinical trial: see the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, regs 29A, 31A; and PARAS 105A, 107A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(5) CLINICAL TRIALS/(iv) Conduct of Clinical Trials/108. Notification of adverse events.

108. Notification of adverse events.

An investigator¹ must report² any serious adverse event³ which occurs in a subject at a trial site at which he is responsible for the conduct of a clinical trial⁴ immediately to the sponsor⁵. Following the immediate report of a serious adverse event, the investigator must make a detailed written report on the event⁶. Where the event reported⁷ consists of, or results in, the death of a subject, the investigator must supply the sponsor⁸ and, in any case where the death has been reported to the relevant ethics committee⁹, that committee¹⁰, with any additional information requested by the sponsor or, as the case may be, the committee¹¹. The sponsor must keep detailed records of all adverse events relating to a clinical trial which are reported to him by the investigators for that trial¹². The licensing authority¹³ may, by sending a notice in writing to the sponsor, require him to send the records, or copies of such records, to the authority¹⁴.

Any person¹⁵ who contravenes these provisions¹⁶ commits an offence¹⁷.

1 For the meaning of 'investigator' see PARA 86 note 2 ante.

2 The reports made under the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 32(1), (3) (see the text to note 6 infra), and reg 32(5) (see note 3 infra) must identify each subject referred to in the report by a number assigned to that subject in accordance with the protocol for the trial: reg 32(6). The number assigned to a subject in accordance with the protocol must be different from the number of any other subject in that trial, including any subject at a trial site outside the United Kingdom: reg 32(7). For the meaning of 'subject' see PARA 82 note 1 ante. For the meaning of 'protocol' see PARA 82 note 2 ante. For the meaning of 'trial site' see PARA 86 note 2 ante. For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

3 The provisions of *ibid* reg 32(1)-(3) do not apply to serious adverse events specified in the protocol or the investigator's brochure as not requiring immediate reporting: reg 32(4). For the meaning of 'investigator's brochure' see PARA 93 note 11 ante. Adverse events, other than those to which the provisions of reg 32(1)-(3) apply, that are identified in the protocol as critical to evaluations of the safety of the trial must be reported to the sponsor in accordance with the reporting requirements, including the time periods for such reporting, specified in that protocol: reg 32(5). See also note 2 supra. For the meaning of 'sponsor' see PARA 82 ante.

'Serious adverse event', 'serious adverse reaction' or 'unexpected serious adverse reaction' means any adverse event, adverse reaction or unexpected adverse reaction, respectively, that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or consists of a congenital anomaly or birth defect; 'adverse event' means any untoward medical occurrence in a subject to whom a medicinal product has been administered, including occurrences which are not necessarily caused by or related to that product; 'adverse reaction' means any untoward and unintended response in a subject to an investigational medicinal product which is related to any dose administered to that subject; and 'unexpected adverse reaction' means an adverse reaction the nature and severity of which is not consistent with the information about the medicinal product in question set out, in the case of a product with a marketing authorisation, in the summary of product characteristics for that product or, in the case of any other investigational medicinal product, in the investigator's brochure relating to the trial in question: Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1). For the meanings of 'medicinal product', 'investigational medicinal product' and 'marketing authorisation' see PARA 82 note 1 ante.

4 As to the meaning of 'conducting a clinical trial' see PARA 86 note 2 ante. For the meaning of 'clinical trial' see PARA 82 ante.

5 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 32(1). Such an immediate report may be made orally or in writing: reg 32(2). See also notes 2, 3 supra. As to infringement notices see PARA 122 post.

6 *Ibid* reg 32(3). See also notes 2, 3 supra.

- 7 le under ibid reg 32(1) (see the text to notes 1-5 supra), reg 32(5) (see note 3 supra).
- 8 Ibid reg 32(8)(a).
- 9 For the meaning of 'relevant ethics committee' see PARA 101 note 20 ante.
- 10 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 32(8)(b).
- 11 Ibid reg 32(8).
- 12 Ibid reg 32(9).
- 13 For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by ibid reg 2(1).
- 14 Ibid reg 32(10). As to the service of notices see PARA 37 note 8 ante; provision applied by reg 47(1).
- 15 For the meaning of 'person' see PARA 21 note 7 ante.
- 16 le the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 32(1), (3), (5)-(9): see the text and notes 1-12 supra.
- 17 Ibid reg 49(1)(g). As to offences generally, defences and penalties see PARAS 123-125 post.

UPDATE

104-111 Conduct of Clinical Trials

The sponsor is required to notify the licensing authority of serious breaches, and is required to keep a trial master file for a clinical trial: see the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, regs 29A, 31A; and PARAS 105A, 107A.

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109. Notification of suspected unexpected serious adverse reactions.

A sponsor¹ must ensure that all relevant information about a suspected unexpected serious adverse reaction² which occurs during the course of a clinical trial³ in the United Kingdom⁴ and is fatal or life-threatening is recorded⁵, and reported as soon as possible to the licensing authority⁶, the competent authorities of any EEA state⁷, other than the United Kingdom, in which the trial is being conducted⁸, and the relevant ethics committee⁹, and in any event not later than seven days after the sponsor was first aware of the reaction¹⁰. A sponsor must ensure that a suspected unexpected serious adverse reaction which occurs during the course of a clinical trial in the United Kingdom, other than those referred to above, is reported as soon as possible to the same bodies, and in any event not later than 15 days after the sponsor is first aware of the reaction¹¹. A sponsor must ensure that, in relation to each clinical trial in the United Kingdom for which he is the sponsor, the investigators¹² responsible for the conduct of a trial are informed of any suspected unexpected serious adverse reaction which occurs in relation to an investigational medicinal product used in that trial, whether that reaction occurs during the course of that trial or another trial for which the sponsor is responsible¹³.

If a clinical trial is being conducted at a trial site¹⁴ in a third country¹⁵ in addition to sites in the United Kingdom, the sponsor of that trial must ensure that all suspected unexpected serious adverse reactions occurring at that site are entered into the European database¹⁶.

Any person¹⁷ who contravenes any of these provisions¹⁸ is guilty of an offence¹⁹.

1 For the meaning of 'sponsor' see PARA 82 ante.

2 For the meaning of 'unexpected serious adverse reaction' see PARA 108 note 3 ante.

3 For the meaning of 'clinical trial' see PARA 82 ante.

4 For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

5 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 33(1)(a).

6 Ibid reg 33(1)(b)(i). For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by reg 2(1).

7 For the meaning of 'EEA state' see PARA 82 note 1 ante.

8 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 33(1)(b)(ii). As to the meaning of 'conducting a clinical trial' see PARA 86 note 2 ante.

9 Ibid reg 33(1)(b)(iii). For the meaning of 'relevant ethics committee' see PARA 101 note 20 ante.

10 Ibid reg 33(1). A sponsor must ensure that within eight days of such a report, any additional relevant information is sent to the persons or bodies listed in reg 33(1): reg 33(2). For the purposes of reg 33(1)-(3) (see the text to note 11 infra), the sponsor may fulfil his obligations to report or provide information to the licensing authority and the competent authorities of any EEA state, other than the United Kingdom, by entering the report or information in the European database established in accordance with EC Parliament and Council Directive 2001/20 (OJ L121, 1.5.2001, p 34) art 11: Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 33(4). The licensing authority must keep a record of all suspected unexpected serious adverse reactions relating to an investigational medicinal product which are brought to its attention, whether pursuant to reg 33(1), (3) or otherwise (reg 33(6)(a)); and ensure that the details of those reactions are entered in the European database established in accordance with EC Parliament and Council Directive 2001/20 (OJ L121, 1.5.2001, p 34) art 11, whether by the sponsor or the authority (Medicines for Human Use (Clinical Trials)).

Regulations 2004, SI 2004/1031, reg 33(6)(b)). For the meaning of 'investigational medicinal product' see PARA 82 note 1 ante. As to infringement notices see PARA 122 post.

11 Ibid reg 33(3). See also note 10 supra.

12 For the meaning of 'investigator' see PARA 86 note 2 ante.

13 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 33(5). As to the authorisation of clinical trials see PARA 95 et seq ante.

14 For the meaning of 'trial site' see PARA 86 note 2 ante.

15 For the meaning of 'third country' see PARA 99 note 5 ante.

16 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 34. The European database is that established in accordance with EC Parliament and Council Directive 2001/20 (OJ L21, 1.5.2001, p 34) art 11: Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 34.

17 For the meaning of 'person' see PARA 21 note 7 ante.

18 Ie the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, regs 33(1)-(5), 34 : see the text and notes 1-16 supra.

19 Ibid reg 49(1)(h), (i). As to offences generally, defences and penalties see PARAS 123-125 post.

UPDATE

104-111 Conduct of Clinical Trials

The sponsor is required to notify the licensing authority of serious breaches, and is required to keep a trial master file for a clinical trial: see the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, regs 29A, 31A; and PARAS 105A, 107A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(5) CLINICAL TRIALS/(iv) Conduct of Clinical Trials/110. Annual list of suspected serious adverse reactions and safety report.

110. Annual list of suspected serious adverse reactions and safety report.

As soon as practicable after the end of the reporting year¹, a sponsor must, in relation to each investigational medicinal product tested in clinical trials in the United Kingdom for which he is the sponsor, furnish the licensing authority and the relevant ethics committees² with: (1) a list of all the suspected serious adverse reactions³ which have occurred during that year in relation to those trials, whether at trial sites⁴ in the United Kingdom or elsewhere⁵, or any other trials relating to that product which are conducted outside the United Kingdom and for which he is the sponsor⁶, including those reactions relating to any investigational medicinal product used as a placebo or as a reference in those trials⁷; and (2) a report on the safety of the subjects⁸ of those trials⁹. Any person who contravenes any of these provisions is guilty of an offence¹⁰.

1 'Reporting year', in relation to an investigational medicinal product, means the year ending on the anniversary of: (1) in the case of a product which has a marketing authorisation, the earliest date on which any such authorisation relating to that product was granted or issued (Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 35(2)(a)); or (2) in any other case, the earliest date on which any clinical trial relating to that product, and for which the person responsible for making the report was the sponsor, was authorised in an EEA state (reg 35(2)(b)). For these purposes, the date on which a clinical trial was authorised in an EEA state is: (a) in the case of the United Kingdom, the date on which the trial was authorised by the licensing authority in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031 (as amended) (reg 35(3)(a)); or (b) in the case of any other EEA state, the date on which the trial was authorised by the competent authority of that EEA state in accordance with EC Parliament and Council Directive 2001/20 (OJ L121, 1.5.2001, p 34) (Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 35(3)(b)). For the meanings of 'investigational medicinal product', 'marketing authorisation' and 'EEA state' see PARA 82 note 1 ante. For the meanings of 'clinical trial' and 'sponsor' see PARA 82 ante. For the meaning of 'person' see PARA 21 note 7 ante. For the meaning of 'United Kingdom' see PARA 7 note 3 ante. For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by reg 2(1). As to the authorisation of clinical trials see PARA 95 et seq ante.

2 For the meaning of 'relevant ethics committee' see PARA 101 note 20 ante.

3 For the meaning of 'serious adverse reaction' see PARA 108 note 3 ante.

4 For the meaning of 'trial site' see PARA 86 note 2 ante.

5 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 35(1)(a)(i).

6 Ibid reg 35(1)(a)(ii).

7 Ibid reg 35(1)(a). As to infringement notices see PARA 122 post.

8 For the meaning of 'subject' see PARA 82 note 1 ante.

9 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 35(1)(b).

10 Ibid reg 49(1)(j). As to offences generally, defences and penalties see PARAS 123-125 post.

UPDATE

104-111 Conduct of Clinical Trials

The sponsor is required to notify the licensing authority of serious breaches, and is required to keep a trial master file for a clinical trial: see the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, regs 29A, 31A; and PARAS 105A, 107A.

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111. Conclusion of clinical trial.

Within 90 days of the conclusion of a clinical trial¹, the sponsor² must notify the licensing authority³ and the relevant ethics committee⁴ in writing that the trial has ended⁵. However, if a trial is terminated⁶ before the date for the conclusion of the trial specified in the protocol⁷ for that trial⁸, or before the event specified in the protocol as the event which indicates the end of the trial has occurred⁹, the sponsor must notify the licensing authority and the relevant ethics committee in writing of the termination of the trial within 15 days of the date of termination¹⁰. A notification¹¹ must contain the specified particulars¹².

A person¹³ who contravenes these provisions is guilty of an offence¹⁴.

1 For the meaning of 'clinical trial' see PARA 82 ante.

2 For the meaning of 'sponsor' see PARA 82 ante.

3 For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1).

4 For the meaning of 'relevant ethics committee' see PARA 101 note 20 ante.

5 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 27(1). As to infringement notices see PARA 122 post.

6 As to the termination of clinical trials by the licensing authority see PARA 107 ante.

7 For the meaning of 'protocol' see PARA 82 note 2 ante.

8 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 27(2)(a).

9 Ibid reg 27(2)(b).

10 Ibid reg 27(2).

11 Ie made in accordance with ibid reg 27(1), (2): see the text and notes 1-10 supra.

12 Ibid reg 27(3). As to the specified particulars see Sch 3 Pt 4.

13 For the meaning of 'person' see PARA 21 note 7 ante.

14 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 49(1)(c). As to offences generally, defences and penalties see PARAS 123-125 post.

UPDATE

104-111 Conduct of Clinical Trials

The sponsor is required to notify the licensing authority of serious breaches, and is required to keep a trial master file for a clinical trial: see the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, regs 29A, 31A; and PARAS 105A, 107A.

111 Conclusion of clinical trial

TEXT AND NOTES--The licensing authority and an ethics committee may disclose to each other any information acquired in carrying out their respective functions under SI 2004/1031 where disclosing such information may assist the other body in carrying out its functions under SI 2004/1031: reg 27A (added by SI 2006/1928).

NOTE 12--Sch 3 Pt 4 amended: SI 2006/1928.

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(v) Manufacture and Importation of Investigational Medicinal Products

112. Requirement for authorisation.

Subject as described below¹, no person² may manufacture³, assemble⁴ or import⁵ any investigational medicinal product except in accordance with an authorisation granted by the licensing authority⁶.

This restriction does not apply: (1) to the manufacture or assembly of a medicinal product to the extent that such manufacture or assembly is in accordance with the terms and conditions of a marketing authorisation⁷ relating to that product⁸; (2) to the assembly of an investigational medicinal product where certain conditions are satisfied⁹. The conditions are that the assembly is carried out in a hospital¹⁰ or health centre¹¹ by a doctor¹², a pharmacist¹³ or a person acting under the supervision of a pharmacist¹⁴, and the investigational medicinal products are assembled exclusively for use in that hospital or health centre¹⁵, or any other hospital or health centre which is a trial site¹⁶ for the clinical trial in which the product is to be used¹⁷.

Any person who contravenes the restriction on the manufacture, assembly or importation of investigational medicinal products¹⁸ is guilty of an offence¹⁹. Similarly, where an investigational medicinal product is manufactured, assembled or imported in contravention of that restriction, any person who sells or supplies the product for the purposes of a clinical trial knowing or having reasonable cause to suspect that it was so manufactured, assembled or imported is guilty of offence²⁰; and, where an investigational medicinal product is imported in contravention of that restriction, any person who, otherwise than for the purpose of performing or exercising a duty or power²¹, is in possession of the product knowing or having reasonable cause to suspect that it was so imported is guilty of offence²².

1 le subject to the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, regs 36(2), 37: see the text to notes 7-17 infra.

2 For the meaning of 'person' see PARA 21 note 7 ante.

3 'Manufacture', in relation to an investigational medicinal product, includes any process carried out in the course of making the product, but does not include dissolving or dispersing the product in, or diluting it or mixing it with, some other substance used as a vehicle for the purposes of administering it: Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1). For the meaning of 'investigational medicinal product' see PARA 82 note 1 ante.

4 'Assemble', in relation to an investigational medicinal product, means: (1) enclosing the product (with or without other medicinal products of the same description) in a container which is labelled before the product is sold or supplied or used in a clinical trial; or (2) where the product (with or without other medicinal products of the same description) is already contained in the container in which it is to be sold or supplied or used in a clinical trial, labelling the container before the product is sold or supplied or used in a clinical trial in that container; and 'assembly' has a corresponding meaning: *ibid* reg 2(1). 'Container', in relation to an investigational medicinal product, means the bottle, jar, box, packet or other receptacle which contains or is to contain it, not being a capsule, cachet or other article in which the product is or is to be administered, and where any such receptacle is or is to be contained in another such receptacle, includes the former but does not include the latter receptacle: reg 2(1). 'Labelling', in relation to an investigational medicinal product, means affixing to or otherwise displaying on it a notice describing or otherwise relating to the contents; and 'label' has a corresponding meaning: reg 2(1). For the meaning of 'medicinal product' see PARA 82 note 1 ante. For the meaning of 'clinical trial' see PARA 82 ante.

- 5 'Import' means import into the United Kingdom from a third country, whether by land, sea or air: *ibid* reg 2(1). For the meaning of 'United Kingdom' see *PARA 7* note 3 *ante*. For the meaning of 'third country' see *PARA 99* note 5 *ante*.
- 6 *Ibid* reg 36(1). Such an authorisation is known as a 'manufacturing authorisation': regs 2(1), 36(1). For the meaning of 'the licensing authority' see *PARA 43* note 8 *ante*; definition applied by reg 2(1).
- 7 For the meaning of 'marketing authorisation' see *PARA 82* note 1 *ante*.
- 8 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 36(2).
- 9 *Ibid* reg 37(1).
- 10 For the meaning of 'hospital' see *PARA 86* note 2 *ante*.
- 11 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 37(2)(a)(i). For the meaning of 'health centre' see *PARA 86* note 2 *ante*.
- 12 For the meaning of 'doctor' see *PARA 86* note 2 *ante*.
- 13 For the meaning of 'pharmacist' see *PARA 86* note 2 *ante*.
- 14 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 37(2)(a)(ii).
- 15 *Ibid* reg 37(2)(b)(i).
- 16 For the meaning of 'trial site' see *PARA 86* note 2 *ante*.
- 17 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 37(2)(b)(ii).
- 18 *Ie* the restriction in *ibid* reg 36(1): see the text to notes 1-6 *supra*.
- 19 *Ibid* reg 49(1)(k). As to offences generally, defences and penalties see *PARAS 123-125 post*.
- 20 *Ibid* reg 49(4). See note 19 *supra*.
- 21 *Ie* a duty or power imposed or conferred by or under the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031 (as amended), the Medicines Act 1968 or any other enactment.
- 22 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 49(5). See note 19 *supra*.

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113. Application for manufacturing authorisation.

An application for the grant of a manufacturing authorisation¹ must be made to the licensing authority² in writing³ and signed by or on behalf of the applicant⁴. Every application for the grant of a manufacturing authorisation must specify which, if any, of the standard provisions⁵ it is desired be excluded or modified in relation to the grant of the authorisation⁶, and must be accompanied by the specified particulars⁷ and any fee which may be payable⁸ in connection with that application⁹. The application and any accompanying material must be supplied to the licensing authority in the English language¹⁰.

Any person¹¹ who, in the course of making an application for the grant of a manufacturing authorisation, provides to the licensing authority any relevant information¹² which is false or misleading in a material particular is guilty of an offence¹³.

1 For the meaning of 'manufacturing authorisation' see PARA 112 note 6 ante.

2 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 38(1)(a). For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by reg 2(1).

3 Ibid reg 38(1)(b).

4 Ibid reg 38(1)(c). As to references to 'signed' see PARA 92 note 11 ante.

5 Ie referred to in ibid reg 40(4): see PARA 115 post.

6 Ibid reg 38(2).

7 Ibid reg 38(3)(a). As to the specified particulars see Sch 6.

8 Ie under the Medicines (Products for Human Use--Fees) Regulations 1995, SI 1995/1116 (as amended): see PARA 11 ante.

9 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 38(3)(b).

10 Ibid reg 38(4).

11 For the meaning of 'person' see PARA 21 note 7 ante.

12 For the meaning of 'relevant information' see PARA 92 note 15 ante.

13 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 50(1)(c). As to offences generally, defences and penalties see PARAS 123-125 post.

UPDATE

113 Application for manufacturing authorisation

NOTE 7--SI 2004/1031 Sch 6 amended: SI 2006/1928.

NOTE 9--However, no fee need accompany an application for the grant of a manufacturing authorisation where arrangements have been made with the licensing authority for the payment of the fee referred to in SI 2004/1031 reg 38(3)(b) other than at the time of the application: reg 38(2A) (added by SI 2006/1928).

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114. Consideration of application for manufacturing authorisation.

The licensing authority¹ must² consider a valid application³ for a manufacturing authorisation⁴ and must grant, or refuse to grant, an authorisation within a period not exceeding 90 days from the date the application is received⁵. Following receipt of an application, the licensing authority may give a notice in writing to the applicant requesting him to provide further information relating to the specified⁶ particulars⁷ or the qualified person⁸.

If the application for a manufacturing authorisation relates, wholly or partially, to the importation⁹ of investigational medicinal products¹⁰, the licensing authority may, if it thinks fit, require the production by the applicant of an undertaking, given by the manufacturer¹¹ of any such products, to permit the premises where they are or are to be manufactured¹², and the operations carried on or to be carried on in the course of manufacturing them¹³, to be inspected by or on behalf of the licensing authority¹⁴.

1 For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1).

2 I.e. subject to ibid reg 39(3) (see note 5 infra), reg 40 (see PARA 115 post).

3 'Valid application' means an application which complies with the provisions of ibid reg 38 (see PARA 113 ante); reg 39(5).

4 For the meaning of 'manufacturing authorisation' see PARA 112 note 6 ante.

5 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 39(1). Where the licensing authority gives a notice pursuant to reg 39(2) (see the text to notes 6-8 infra), the period for granting or refusing to grant an authorisation is suspended from the date the notice is given and recommences only on receipt of the information requested: reg 39(3).

6 I.e. specified in ibid reg 38(3): see PARA 113 ante.

7 Ibid reg 39(2)(a). See also note 5 supra.

8 Ibid reg 39(2)(b). See also note 5 supra. For the meaning of 'qualified person' see PARA 118 note 2 post. It is an offence for a person to provide false or misleading information in response to such a notice: see reg 50(1)(c); and PARA 113 ante. As to the service of notices see PARA 37 note 8 ante; provision applied by reg 47(1).

9 For the meaning of 'import' see PARA 112 note 5 ante.

10 For the meaning of 'investigational medicinal product' see PARA 82 note 1 ante.

11 As to the meaning of 'manufacturer' see PARA 112 note 3 ante.

12 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 39(4)(a).

13 Ibid reg 39(4)(b).

14 Ibid reg 39(4).

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115. Grant or refusal of manufacturing authorisation.

The licensing authority¹ must grant a manufacturing authorisation² only if:

- 94 (1) the applicant: (a) has complied with the requirements³ relating to applications⁴; (b) has at his disposal suitable and sufficient premises, technical equipment and control facilities complying with specified requirements⁵, as regards the manufacture⁶ or import⁷, and control, of the products to which the authorisation relates and the storage of such products⁸; (c) has at his disposal the services of at least one qualified person⁹; and (d) if a notice has been given¹⁰ requesting further information, has provided the information requested by the licensing authority¹¹; and
- 95 (2) it has established that the particulars supplied¹² with the application are accurate¹³.

Subject to these provisions, the licensing authority may grant a manufacturing authorisation in respect of any or all of the descriptions of investigational medicinal products¹⁴, the manufacturing, assembling¹⁵ or importation operations¹⁶, or the premises¹⁷, specified in the application¹⁸. The licensing authority may grant a manufacturing authorisation containing any of the specified provisions¹⁹ to be incorporated in the authorisation²⁰, or such other provisions as the licensing authority considers appropriate²¹.

Where the licensing authority refuses to grant a manufacturing authorisation²², or grants a manufacturing authorisation otherwise than in accordance with the application²³, and the applicant requests the authority to state its reasons, the authority must give the applicant a notice in writing stating the reasons for its decision²⁴.

1 For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1).

2 For the meaning of 'manufacturing authorisation' see PARA 112 note 6 ante. As to the consideration, grant or refusal of such authorisations see PARAS 114-115 ante. As to the requirement for such authorisations see PARA 112 ante.

3 Ie the requirements of the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 38: see PARA 113 ante.

4 Ibid reg 40(1)(a)(i).

5 Ie the requirements of EC Commission Directive 2003/94 (OJ L262, 14.10.2003, p 22) laying down the principles and guidelines of good manufacturing practice for medicinal products for human use and for investigational medicinal products for human use.

6 As to the meaning of 'manufacture' see PARA 112 note 3 ante.

7 For the meaning of 'import' see PARA 112 note 5 ante.

8 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 40(1)(a)(ii).

9 Ibid reg 40(1)(a)(iii). For the meaning of 'qualified person' see PARA 118 note 2 post.

10 Ie under ibid reg 39(2): see PARA 114 ante.

- 11 Ibid reg 40(1)(a)(iv).
- 12 Ie pursuant to ibid reg 38(3): see PARA 113 ante.
- 13 Ibid reg 40(1)(b).
- 14 Ibid reg 40(2)(a). For the meaning of 'investigational medicinal product' see PARA 82 note 1 ante.
- 15 For the meaning of 'assemble' see PARA 112 note 4 ante.
- 16 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 40(2)(b).
- 17 Ibid reg 40(2)(c).
- 18 Ibid reg 40(2).
- 19 The provisions specified:
 - 64 (1) in the case of a manufacturing authorisation relating to the manufacture or assembly of investigational medicinal products, in ibid Sch 7 Pt 2 (reg 40(4)(a)); and
 - 65 (2) in the case of a manufacturing authorisation relating to the importation of investigational medicinal products, in Sch 7 Pt 3 (reg 40(4)(b)),may be incorporated by the licensing authority in any manufacturing authorisation, with or without modifications, and either generally or in relation to investigational medicinal products of any particular class (reg 40(4)).
- 20 Ibid reg 40(3)(a).
- 21 Ibid reg 40(3)(b).
- 22 Ibid reg 40(6)(a).
- 23 Ibid reg 40(6)(b).
- 24 Ibid reg 40(6). As to the service of notices see PARA 37 note 8 ante; provision applied by reg 47(1). As to the procedure where the licensing authority refuses to grant a manufacturing authorisation or grants a manufacturing authorisation otherwise than in accordance with the application see PARA 116 post.

UPDATE

115 Grant or refusal of manufacturing authorisation

TEXT AND NOTE 5--After 'his disposal' read 'the services of staff, and': SI 2004/1031 reg 40(1)(a)(ii) (substituted by SI 2006/1928).

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116. Procedural provisions.

If the licensing authority¹ proposes:

- 96 (1) not to grant a manufacturing authorisation²;
- 97 (2) to grant an authorisation other than in accordance with the application³; or
- 98 (3) to revoke, vary or suspend an authorisation⁴,

the authority must notify the applicant or holder⁵ accordingly⁶.

The applicant or holder to whom notice is given may, within the time allowed⁷ after the notification was given, notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority with respect to the decision⁸, or make representations in writing to the licensing authority with respect to the decision referred to in the notice⁹. If the applicant or holder makes written representations, the licensing authority must take those representations into account before deciding whether to grant the authorisation¹⁰, revoke, vary or suspend the authorisation¹¹, or confirm or alter its decision¹², as the case may be¹³.

If the applicant or holder gives notice of his wish to appear before or be heard by a person appointed by the licensing authority, the authority must make that appointment¹⁴ and arrange for the applicant or holder who gave notice to have an opportunity of appearing before the person appointed¹⁵. The applicant or holder must, before the end of the period of three months beginning with the date of his notice¹⁶, provide the person appointed with a written summary of the oral representations he intends to make¹⁷ and any documents on which he wishes to rely in support of those representations¹⁸. If the applicant or holder fails to comply with the time limit, or any extended time limit, he may not appear before or be heard by the person appointed¹⁹ and the licensing authority must decide whether to grant the authorisation, revoke, vary or suspend the authorisation, or confirm or alter its decision, as the case may be²⁰.

At the hearing before the person appointed, both the applicant or holder and the licensing authority may make representations²¹ and, if the applicant or holder so requests, the hearing must be in public²². After the hearing, the person appointed must provide a report to the licensing authority²³, and the licensing authority must take this report into account and decide whether to grant the authorisation, revoke, vary or suspend the authorisation, or confirm or alter its decision, as the case may be²⁴. The licensing authority must then notify the applicant or holder of its decision²⁵ and, if the applicant or holder so requests, provide him with a copy of the report of the person appointed²⁶.

1 For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1).

2 Ibid reg 40(5), Sch 8 para 2(a). For the meaning of 'manufacturing authorisation' see PARA 112 note 6 ante. As to the requirement for such authorisations see PARA 112 ante. As to applications for such authorisations and the determination of applications see PARAS 113-115 ante.

3 Ibid Sch 8 para 2(b).

4 Ibid regs 44(6), 45(3), Sch 8 para 2(c). Schedule 8 para 2 does not apply to the suspension of an authorisation where it appears to the licensing authority that, in the interests of safety, it is necessary to suspend the authorisation with immediate effect for a period not exceeding three months: Sch 8 para 6(1). If,

after the suspension has taken effect, it appears to the licensing authority that the authorisation should be further suspended or revoked, the licensing authority must proceed in accordance with Sch 8 paras 2-5 (see the text and notes 6-13 *infra*): Sch 8 para 6(2). As to the variation of an authorisation see PARA 119 *post*; and as to the suspension and revocation of authorisations see PARA 120 *post*.

5 Any reference to the holder of a manufacturing authorisation must be construed as a reference to the holder of such an authorisation which is for the time being in force: *ibid* reg 2(2).

6 *Ibid* Sch 8 para 2. Any such notification must include a statement of the proposals of the licensing authority and of the reasons for them: Sch 8 para 3.

7 'Time allowed' means the period of 28 days or such extended period as the licensing authority may in any particular case allow: *ibid* Sch 8 para 1.

8 *Ibid* Sch 8 para 4(1)(a) (Sch 8 paras 4, 5 substituted by SI 2005/2754).

9 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, Sch 8 para 4(1)(b) (as substituted: see note 8 *supra*).

10 *Ibid* Sch 8 para 4(2)(a) (as substituted: see note 8 *supra*).

11 *Ibid* Sch 8 para 4(2)(b) (as substituted: see note 8 *supra*).

12 *Ibid* Sch 8 para 4(2)(c) (as substituted: see note 8 *supra*).

13 *Ibid* Sch 8 para 4(2) (as substituted: see note 8 *supra*).

14 *Ibid* Sch 8 para 5(1)(a) (as substituted: see note 8 *supra*). The person appointed must not be, or at any time have been, a member of the Commission on Human Medicines or any of its expert advisory groups, the former Medicines Commission or any of its committees, or a committee established under the Medicines Act 1968 s 4 (see PARA 15 *ante*) or any sub-committee of such a committee (Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, Sch 8 para 5(2)(a)(i)-(iii) (as so substituted)); and must not be an officer or servant of a Minister of the Crown (Sch 8 para 5(2)(b) (as so substituted)). As to the Commission on Human Medicines see PARA 13 *et seq ante*; and as to the former Medicines Commission see PARA 13 note 1 *ante*. As to expert advisory groups see PARA 17 *ante*. As to Ministers of the Crown see CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARA 354 *et seq*.

15 *Ibid* Sch 8 para 5(1)(b) (as substituted: see note 8 *supra*).

16 If the applicant or holder so requests, the person appointed may, after consulting the licensing authority, extend the time limit up to a maximum period of six months beginning with the date of the notice: *ibid* Sch 8 para 5(4) (as substituted: see note 8 *supra*). The applicant or holder may not submit any additional written representations or documents once the time limit has expired, except with the permission of the person appointed: Sch 8 para 5(6) (as so substituted). For the meaning of 'month' see PARA 22 note 15 *ante*.

17 *Ibid* Sch 8 para 5(3)(a) (as substituted: see note 8 *supra*).

18 *Ibid* Sch 8 para 5(3)(b) (as substituted: see note 8 *supra*).

19 *Ibid* Sch 8 para 5(5)(a) (as substituted: see note 8 *supra*).

20 *Ibid* Sch 8 para 5(5)(b) (as substituted: see note 8 *supra*).

21 *Ibid* Sch 8 para 5(7) (as substituted: see note 8 *supra*).

22 *Ibid* Sch 8 para 5(8) (as substituted: see note 8 *supra*).

23 *Ibid* Sch 8 para 5(9)(a) (as substituted: see note 8 *supra*).

24 *Ibid* Sch 8 para 5(9)(b) (as substituted: see note 8 *supra*).

25 *Ibid* Sch 8 para 5(10)(a) (as substituted: see note 8 *supra*).

26 *Ibid* Sch 8 para 5(10)(b) (as substituted: see note 8 *supra*).

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117. Application and effect of manufacturing authorisation.

A manufacturing authorisation¹ applies only in relation to the descriptions of investigational medicinal products², the manufacturing³, assembling⁴ or importation⁵ operations⁶, and the premises⁷, specified in the application⁸ and in respect of which the authorisation is granted⁹. The holder of a manufacturing authorisation¹⁰ must comply with the principles and guidelines of good manufacturing practice¹¹ and the provisions¹² subject to which the authorisation is granted¹³. Any person¹⁴ who contravenes these provisions is guilty of an offence¹⁵.

1 For the meaning of 'manufacturing authorisation' see PARA 112 note 6 ante.

2 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 41(a). For the meaning of 'investigational medicinal product' see PARA 82 note 1 ante.

3 As to the meaning of 'manufacture' see PARA 112 note 3 ante.

4 For the meaning of 'assemble' see PARA 112 note 4 ante.

5 For the meaning of 'import' see PARA 112 note 5 ante.

6 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 41(b).

7 Ibid reg 41(c).

8 Ie the application made pursuant to ibid reg 38: see PARA 113 ante.

9 Ibid reg 41. As to the requirement for such authorisations see PARA 112 ante. As to the determination of applications see PARAS 114-116 ante.

10 As to references to 'the holder of a manufacturing authorisation' see PARA 116 note 5 ante.

11 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 42(a). 'The principles and guidelines of good manufacturing practice' means the principles and guidelines of good manufacturing practice set out in EC Commission Directive 2003/94 (OJ L262, 14.10.2003, p 22): Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1).

12 Ie the provisions referred to in ibid reg 40(3): see PARA 115 ante.

13 Ibid reg 42(b).

14 For the meaning of 'person' see PARA 21 note 7 ante.

15 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 49(1)(l). As to offences generally, defences and penalties see PARAS 123-125 post.

UPDATE

117 Application and effect of manufacturing authorisation

TEXT AND NOTE 6--After 'operations' read 'in the case of an authorisation relating to the inactivation of viral or non-conventional agents, the manufacturing process': SI 2004/1031 reg 41(bb) (added by SI 2006/1928).

TEXT AND NOTES 11-13--Further, the holder of a manufacturing authorisation must allow the licensing authority access to his premises at any reasonable time, and put and keep in place arrangements which enable the qualified person to carry out his duties, including placing at his disposal all the necessary facilities: SI 2004/1031 reg 42(c), (d) (reg 42 substituted by SI 2006/1928).

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118. Qualified persons.

The holder of a manufacturing authorisation¹ must have at his disposal the services of at least one qualified person² who is responsible for carrying out the specified duties³ in respect of the investigational medicinal products manufactured⁴, assembled⁵ or imported⁶ in accordance with the authorisation in question⁷. If the holder of the authorisation satisfies the requirements as to qualifications and experience⁸, he may act as the qualified person for the purposes of that authorisation⁹. A qualified person must perform his functions in accordance with the Code of Practice for Qualified Persons in the Pharmaceutical Industry, published jointly by the Institute of Biology, the Royal Pharmaceutical Society of Great Britain and the Royal Society of Chemistry in March 2004¹⁰.

Where, after giving the holder of the authorisation and the person acting as a qualified person the opportunity of making representations to it, orally or in writing, the licensing authority is of the opinion that:

- 99 (1) the person so acting does not satisfy the provisions¹¹ or requirements¹² as respects qualifications and experience¹³; or
- 100 (2) he is failing to carry out the duties¹⁴ of a qualified person adequately or at all¹⁵,

and has notified the holder of the authorisation accordingly in writing, the holder of the authorisation must not permit that person to act as a qualified person¹⁶.

Any person¹⁷ who contravenes the requirement to have at his disposal the services of a qualified person¹⁸ or not to permit a person to act as a qualified person¹⁹ commits an offence²⁰; and any person who, for the purpose of being engaged as a qualified person, provides to the licensing authority or to the holder of a manufacturing authorisation any information which is false or misleading in a material particular is guilty of an offence²¹.

1 As to references to 'the holder of a manufacturing authorisation' see PARA 116 note 5 ante.

2 'Qualified person' means:

66 (1) a person who as respects qualifications and experience satisfies the requirements of European Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 49 or 50 (Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1)); or

67 (2) a person who, without satisfying those requirements:

13. (a) has been engaged in activities equivalent to those to be performed in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 43(2) (see the text to notes 4-7 infra) in respect of investigational medicinal products for a period of at least six months prior to 1 May 2004 (reg 2(1));

13

14. (b) has, in accordance with Sch 6 para 6(1) (see PARA 113 ante), been named as a qualified person in a valid application for a manufacturing authorisation made prior to 1 May 2006 (reg 2(1)); and

14

15. (c) is a member of the Institute of Biology, the Pharmaceutical Society, the Royal Society of Chemistry, or such other body as may appear to the licensing authority to be an appropriate body for these purposes, or is the holder of a diploma, certificate or other evidence of formal qualifications awarded on completion

of a university or other higher education course of study in pharmacy, chemistry, medicine, biology or a related life science, which the licensing authority has stated in a notice in writing to that person to be qualifications sufficient for the purpose of performing the functions of a qualified person (reg 2(1)).

15

The holder of the authorisation may regard a person as satisfying the provisions of European Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 49 or 50 as respects formal qualifications if he produces evidence that he is a member of the Institute of Biology, the Pharmaceutical Society, the Royal Society of Chemistry, or such other body as may appear to the licensing authority to be an appropriate body for these purposes, and he is regarded by the body of which he is a member as satisfying those provisions: Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 43(5). This provision is expressed to be without prejudice to reg 43(6): see the text to notes 11-16 infra.

For the meaning of 'investigational medicinal product' see PARA 82 note 1 ante. For the meaning of 'manufacturing authorisation' see PARA 112 note 6 ante. 'Pharmaceutical Society' in relation to Great Britain means the Royal Pharmaceutical Society of Great Britain, and in relation to Northern Ireland means the Pharmaceutical Society of Northern Ireland: reg 2(1). As to the Royal Pharmaceutical Society of Great Britain see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 881 et seq. For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by reg 2(1). As to the service of notices see PARA 37 note 8 ante; provision applied by reg 47(1).

3 Ibid reg 43(1). The specified duties are those specified in EC Parliament and Council Directive 2001/20 (OJ L121, 1.5.2001, p 34) art 13(3), (4), carried out in accordance with that article: Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 43(2).

4 As to the meaning of 'manufacture' see PARA 112 note 3 ante.

5 For the meaning of 'assemble' see PARA 112 note 4 ante.

6 For the meaning of 'import' see PARA 112 note 5 ante.

7 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 43(2). As to the requirement for such authorisations see PARA 112 ante; and as to the determination of applications for authorisations see PARAS 114-116 ante. As to the application and effect of authorisations see PARA 117 ante.

8 Ie as specified in head (1) or head (2) of the definition of 'qualified person': see note 2 supra.

9 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 43(4).

10 Ibid reg 43(3). A copy of the Code of Practice may be obtained by writing to the Institute of Biology, 20 Queensbury Place, London SW7 2DZ; the Royal Pharmaceutical Society of Great Britain, 1 Lambeth High Street, London SE1 7JN; or the Royal Society of Chemistry, Burlington House, Piccadilly, London W1V 0BN.

11 Ie the provisions of European Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) arts 49, 50.

12 Ie as specified in head (2) of the definition of 'qualified person': see note 2 supra.

13 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 43(6)(a)(i), (ii).

14 Ie referred to in ibid reg 43(2): see the text to notes 4-7 supra.

15 Ibid reg 43(6)(b).

16 Ibid reg 43(6).

17 For the meaning of 'person' see PARA 21 note 7 ante.

18 Ie under the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 43(1): see the text to notes 1-3 supra.

19 Ie under ibid reg 43(6): see the text to notes 11-16 supra.

20 Ibid reg 49(1)(m). As to offences generally, defences and penalties see PARAS 123-125 post.

21 Ibid reg 50(3). See note 20 supra.

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119. Variation of manufacturing authorisation.

The licensing authority¹ may vary a manufacturing authorisation², whether on the application of the holder of the authorisation³ or otherwise⁴. If the holder of a manufacturing authorisation makes a valid application⁵ to vary the manufacturing authorisation, the licensing authority must consider the application and, in a case where the effect of the variation would be to change the types of investigational medicinal products⁶, the manufacturing⁷, assembling⁸ or importation⁹ operations¹⁰, the premises¹¹, or the technical equipment and control facilities¹², in respect of which the authorisation has been granted, may vary or refuse to vary the authorisation within a period not exceeding 30 days from the date the application is received¹³. In any other case, the authority may vary or refuse to vary the authorisation within such period as it considers appropriate¹⁴. Following receipt of a valid application to vary a manufacturing authorisation, the licensing authority may give a notice in writing to the applicant requesting him to provide further information relating to the contents of the application or any particulars relevant to the application¹⁵. Where the licensing authority varies a manufacturing authorisation otherwise than in accordance with a valid application by the holder of the authorisation¹⁶ or, after consideration of such an application, refuses to vary a manufacturing authorisation¹⁷, the licensing authority must notify the holder of that authorisation in writing, stating the reasons for its decision¹⁸.

Any person¹⁹ who in the course of making an application for the variation of a manufacturing authorisation provides to the licensing authority any relevant information²⁰ which is false or misleading in a material particular is guilty of an offence²¹.

1 For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1).

2 For the meaning of 'manufacturing authorisation' see PARA 112 note 6 ante. As to the requirement for manufacturing authorisations see PARA 112 ante; and as to the application and effect of authorisations see PARA 117 ante. As to applications for authorisations and their determination see PARAS 113-116 ante.

3 As to references to 'the holder of a manufacturing authorisation' see PARA 116 note 5 ante.

4 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 44(1). The provisions of Sch 8 (see PARA 116 ante) have effect where the licensing authority proposes to vary a manufacturing authorisation otherwise than on the application of the holder of the authorisation: reg 44(6).

5 'Valid application' means an application made to the licensing authority, in writing and signed by or on behalf of the applicant, specifying the variation requested by the applicant, accompanied by such particulars as are necessary to enable the licensing authority to consider the application, and any fee which may be payable in connection with that application under the Medicines (Products for Human Use--Fees) Regulations 1995, SI 1995/1116 (as amended) (see PARA 11 ante); and the application and any accompanying material must be in the English language: Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 44(8). As to references to 'signed' see PARA 92 note 11 ante.

6 Ibid reg 44(2)(a)(i). For the meaning of 'investigational medicinal product' see PARA 82 note 1 ante.

7 As to the meaning of 'manufacture' see PARA 112 note 3 ante.

8 For the meaning of 'assemble' see PARA 112 note 4 ante.

9 For the meaning of 'import' see PARA 112 note 5 ante.

10 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 44(2)(a)(ii).

11 Ibid reg 44(2)(a)(iii).

12 Ibid reg 44(2)(a)(iv).

13 Ibid reg 44(2)(a). If the application falls within reg 44(2)(a), but it appears to the licensing authority to be necessary to conduct an inspection of any premises to which the variation relates, the authority may vary or refuse to vary the authorisation within a period not exceeding 90 days from the date the application is received: reg 44(3). See also note 15 *infra*.

14 Ibid reg 44(2)(b).

15 Ibid reg 44(4). Where the licensing authority gives such a notice, and a period specified in reg 44(2)(a), (3) (see the text and note 13 *supra*) applies, that period is suspended from the date the notice is given and recommences only on receipt of the information requested: reg 44(5). As to the service of notices see PARA 37 note 8 *ante*; provision applied by reg 47(1).

16 Ibid reg 44(7)(a).

17 Ibid reg 44(7)(b).

18 Ibid reg 44(7).

19 For the meaning of 'person' see PARA 21 note 7 *ante*.

20 For the meaning of 'relevant information' see PARA 92 note 15 *ante*.

21 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 50(1)(c). As to offences generally, defences and penalties see PARAS 123-125 *post*.

UPDATE

119 Variation of manufacturing authorisation

NOTE 5--Definition of 'valid application' amended: SI 2004/1031 reg 44(8) (substituted by SI 2006/1928).

TEXT AND NOTE 12--After 'control facilities' read 'the manufacturing process, or the staff, including the qualified person': SI 2004/1031 reg 44(2)(a)(iia), (v) (added by SI 2006/1928).

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120. Suspension and revocation of manufacturing authorisation.

The licensing authority¹ may by a notice in writing to the holder of a manufacturing authorisation², forthwith or from a date specified in the notice, suspend the authorisation for such period as the authority may determine, or revoke the authorisation, on one or more of the following grounds³:

- 101 (1) the holder is not carrying out, or has indicated by a notice in writing that he is no longer to carry out, the manufacturing⁴, assembly⁵ or importation⁶ operations to which the authorisation relates⁷;
 - 102 (2) the particulars accompanying the application⁸ were false or incomplete in a material particular⁹;
 - 103 (3) a material change of circumstances has occurred in relation to any of those matters or particulars¹⁰;
 - 104 (4) the holder of the authorisation has failed to any material extent to comply with his obligations in relation to the authorisation¹¹ or the availability of the services of a qualified person¹²;
 - 105 (5) the holder has manufactured, assembled or, as the case may be, imported investigational medicinal products¹³ otherwise than in accordance with the terms of the authorisation¹⁴;
 - 106 (6) the holder has manufactured or assembled investigational medicinal products otherwise than in accordance with:
- 15
- 15. (a) in the case of products manufactured before a request for authorisation to conduct the clinical trial¹⁵ involving those products has been made¹⁶, the specification for the product provided by the person¹⁷ who is to act as the sponsor¹⁸ of the proposed clinical trial¹⁹;
 - 16. (b) in the case of products manufactured for the purpose of export²⁰, the specification for the product provided by the person to whose order the products are manufactured²¹; or
 - 17. (c) in any other case, the specification for the product contained in the investigational medicinal product dossier²² for that product²³;
- 16
- 107 (7) the qualified person²⁴ has failed to carry out his duties²⁵ adequately or at all²⁶; and
 - 108 (8) the holder of the authorisation does not have the staff, premises, equipment or facilities necessary for carrying out properly:
- 17
- 18. (a) the manufacture or assembly operations to which the authorisation relates²⁷; or
 - 19. (b) the importation operations to which the authorisation relates²⁸,
- 18
- 109 including any handling, storage or distribution activities relating to those operations²⁹.

The suspension or revocation of an authorisation may be total³⁰, or limited to investigational medicinal products of one or more descriptions³¹ or manufactured, assembled or stored on any particular premises or in a particular part of any premises³². Where the licensing authority suspends or revokes a manufacturing authorisation, it must notify the holder of that authorisation in writing, stating the reasons for its decision to suspend or revoke the authorisation³³.

1 For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 2(1).

2 For the meaning of 'manufacturing authorisation' see PARA 112 note 6 ante. As to references to 'the holder of a manufacturing authorisation' see PARA 116 note 5 ante. As to the requirement for manufacturing authorisations see PARA 112 ante; and as to the application and effect of authorisations see PARA 117 ante. As to applications for authorisations and their determination see PARAS 113-116 ante. As to the service of notices see PARA 37 note 8 ante; provision applied by *ibid* reg 47(1).

3 *Ibid* reg 45(1). The provisions of Sch 8 (see PARA 116 ante) have effect where the licensing authority proposes to suspend or revoke a manufacturing authorisation: reg 45(3).

4 As to the meaning of 'manufacture' see PARA 112 note 3 ante.

5 For the meaning of 'assembly' see PARA 112 note 4 ante.

6 For the meaning of 'import' see PARA 112 note 5 ante.

7 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 45(1)(a).

8 *Ie* in accordance with *ibid* reg 38(3): see PARA 113 ante.

9 *Ibid* reg 45(1)(b). As to the offence of providing false or misleading information in relation to an application see PARA 113 ante.

10 *Ibid* reg 45(1)(c).

11 *Ie* under *ibid* reg 42: see PARA 117 ante.

12 *Ibid* reg 45(1)(d). The obligations in relation to a qualified person are those under reg 43(1): see PARA 118 ante.

13 For the meaning of 'investigational medicinal product' see PARA 82 note 1 ante.

14 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 45(1)(e).

15 For the meaning of 'clinical trial' see PARA 82 ante.

16 *Ie* in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 17 (see PARA 95 ante) or any equivalent provisions in any EEA state other than the United Kingdom: reg 45(1)(f)(i). For the meaning of 'EEA state' see PARA 82 note 1 ante. For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

17 For the meaning of 'person' see PARA 21 note 7 ante.

18 For the meaning of 'sponsor' see PARA 82 ante.

19 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 45(1)(f)(i).

20 'Export' means export to a third country from an EEA state, whether by land, sea or air: *ibid* reg 2(1). For the meaning of 'third country' see PARA 99 note 5 ante.

21 *Ibid* reg 45(1)(f)(ii).

22 'Investigational medicinal product dossier' means, in relation to an investigational medicinal product, the dossier relating to that product which accompanies a request for authorisation to conduct a trial in which that product is or is to be used, in accordance with *ibid* reg 17(2), Sch 3 para 11 (see PARA 95 ante): reg 2(1).

23 *Ibid* reg 45(1)(f)(iii).

24 For the meaning of 'qualified person' see PARA 118 note 2 ante.

25 le as referred to in the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 43(2): see PARA 118 ante.

26 Ibid reg 45(1)(g).

27 Ibid reg 45(1)(h)(i).

28 Ibid reg 45(1)(h)(ii).

29 Ibid reg 45(1)(h).

30 Ibid reg 45(2)(a).

31 Ibid reg 45(2)(b)(i).

32 Ibid reg 45(2)(b)(ii).

33 Ibid reg 45(4).

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121. Labelling.

An investigational medicinal product¹ must be labelled² in accordance with the specified provisions³. However, this does not apply where the investigational medicinal product is for use in a clinical trial⁴ with the specified characteristics⁵, dispensed to a subject⁶ in accordance with a prescription given by an authorised health care professional⁷, and labelled in accordance with the requirements⁸ that apply in relation to dispensed relevant medicinal products⁹.

Any sponsor¹⁰ who sells or supplies, or procures the sale or supply, of an investigational medicinal product to a subject for the purposes of a clinical trial¹¹, or to a person for the purpose of administering the product to such a subject¹², the labelling of which does not comply with these provisions, is guilty of an offence¹³. Any person¹⁴ who sells or supplies an investigational medicinal product to a subject for the purposes of a clinical trial¹⁵, or to a person for the purpose of administering the product to such a subject¹⁶, the labelling of which does not comply with these provisions, knowing, or having reasonable cause to believe, that the labelling does not so comply, is also guilty of an offence¹⁷.

1 For the meaning of 'investigational medicinal product' see PARA 82 note 1 ante.

2 For the meaning of 'label' see PARA 112 note 4 ante.

3 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 46(1). The specified provisions are those of EC Commission Directive 2003/94 (OJ L262, 14.10.2003, p 22) art 15: Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 46(1).

4 For the meaning of 'clinical trial' see PARA 82 ante.

5 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 46(2)(a). The characteristics are those specified in EC Parliament and Council Directive 2001/20 (OJ L21, 1.5.2001, p 34) art 14 (second paragraph): Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 46(2)(a).

6 For the meaning of 'subject' see PARA 82 note 1 ante.

7 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 46(2)(b). For the meaning of 'health care professional' see PARA 86 note 2 ante.

8 Ie the requirements of the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144, Sch 5: see PARA 23 ante.

9 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 46(2)(c).

10 For the meaning of 'sponsor' see PARA 82 ante.

11 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 49(6)(a).

12 Ibid reg 49(6)(b).

13 Ibid reg 49(6). As to offences generally, defences and penalties see PARAS 123-125 post.

14 For the meaning of 'person' see PARA 21 note 7 ante.

15 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 49(7)(a).

16 Ibid reg 49(7)(b).

17 Ibid reg 49(7). See note 13 supra.

UPDATE

121 Labelling

TEXT AND NOTE 7--Word 'authorised' omitted: SI 2004/1031 reg 46(2)(b) (amended by SI 2006/1928).

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(vi) Enforcement

122. Enforcement.

The enforcement provisions of the Medicines Act 1968¹ apply for the purposes of the clinical trials regulations², with modifications³.

If an enforcement authority⁴ has objective grounds for considering that any person⁵ has contravened any of the provisions relating to the amendment of a clinical trial authorisation⁶, the notification of the conclusion of a clinical trial⁷, the conduct of a trial⁸, urgent safety measures⁹, or the notification of adverse events¹⁰, it may serve upon that person a notice in writing, known as an 'infringement notice'¹¹. The notice must inform the person of the authority's grounds for considering that he has contravened one or more of those provisions¹²; specify the relevant provision¹³ and the measures which he must take in order to ensure that the contravention does not continue or, as the case may be, does not recur¹⁴; require him to take those measures within such period as may be specified in the notice¹⁵; and warn him that unless those requirements are met further action may be taken in respect of the contravention¹⁶.

If an enforcement authority serves an infringement notice, it must forthwith inform the competent authorities of each EEA state¹⁷ other than the United Kingdom¹⁸, the relevant ethics committee¹⁹ and the European Commission²⁰.

1 Ie the Medicines Act 1968 ss 107-116 (see PARAS 79 ante, 168-173 post), ss 118-119 (see PARAS 174-175 post), ss 121-125 (see PARAS 179-181, 183 post), s 127 (see PARA 37 note 8 ante), s 129 (see PARA 5 ante), s 131 (see PARAS 7, 47 ante), s 132(1) and Sch 3 (see PARAS 170-171 post).

2 Ie the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031 (as amended).

3 Ibid reg 47(1). As to the modifications see Sch 9. In those provisions as applying by virtue of reg 47(1), a reference to any part of those provisions or a part of any of them is a reference to the provision or part as so applying; reg 47(2).

4 'Enforcement authority' means any minister or body on whom a duty or power to enforce any provisions of the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031 (as amended) is imposed or conferred by or under the Medicines Act 1968 s 108 (see PARA 168 post) as applied by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 47 (see the text to notes 1-3 supra); reg 48(5).

5 For the meaning of 'person' see PARA 21 note 7 ante.

6 Ie under the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 22(b): see PARA 101 ante.

7 Ie under ibid reg 27: see PARA 111 ante.

8 Ie under ibid regs 28(1)-(3), 29: see PARAS 104-105 ante.

9 Ie under ibid reg 30(2): see PARA 106 ante.

10 Ie under ibid regs 32-35: see PARAS 108-110 ante.

11 Ibid reg 48(1), (4). As to the service of notices see PARA 37 note 8 ante; provision applied by reg 47(1) (see the text to notes 1-3 supra).

12 Ibid reg 48(1)(a).

13 Ibid reg 48(1)(b).

14 Ibid reg 48(1)(c). An infringement notice may include directions as to the measures to be taken by the person on whom the notice is served to ensure that the contravention does not continue or, as the case may be, does not recur, including the different ways of securing compliance: reg 48(2).

15 Ibid reg 48(1)(d).

16 Ibid reg 48(1)(e).

17 For the meaning of 'EEA state' see PARA 82 note 1 ante.

18 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 48(3)(a). For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

19 Ibid reg 48(3)(b). For the meaning of 'relevant ethics committee' see PARA 101 note 20 ante.

20 Ibid reg 48(3)(c).

UPDATE

122 Enforcement

NOTE 3--SI 2004/1031 Sch 9 amended: SI 2006/1928.

TEXT AND NOTES 6-11--An infringement notice may also be served in respect of SI 2004/1031 reg 3A (sponsor's responsibility for investigator's brochure), reg 12(1) (favourable opinion in relation to the clinical trial by ethics committee and authorisation by the licensing authority), reg 29A (notification for serious breaches: see PARA 105A), and reg 31A (trial master file: see PARA 107A): reg 48(4) (amended by SI 2006/1928).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(5) CLINICAL TRIALS/(vi) Enforcement/123. False or misleading information.

123. False or misleading information.

Any person¹ who:

- 110 (1) is conducting an authorised² clinical trial³;
- 111 (2) is a sponsor⁴ of such a clinical trial⁵;
- 112 (3) while acting under arrangements made with a sponsor of such a clinical trial, performs the functions of that sponsor⁶; or
- 113 (4) holds a manufacturing authorisation⁷,

and who⁸ provides to the licensing authority⁹ or an ethics committee¹⁰ any relevant information¹¹ which is false or misleading in a material particular is guilty of an offence¹².

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 Is authorised in accordance with the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031 (as amended). As to authorisations for clinical trials see PARA 95 et seq ante.

3 Ibid reg 50(2)(a). As to the meaning of 'conducting a clinical trial' see PARA 86 note 2 ante. For the meaning of 'clinical trial' see PARA 82 ante.

4 For the meaning of 'sponsor' see PARA 82 ante.

5 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 50(2)(b).

6 Ibid reg 50(2)(c).

7 Ibid reg 50(2)(d). As to references to 'the holder of a manufacturing authorisation' see PARA 116 note 5 ante. For the meaning of 'manufacturing authorisation' see PARA 112 note 6 ante.

8 Is for the purposes of the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031 (as amended).

9 For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by ibid reg 2(1).

10 For the meaning of 'ethics committee' see PARA 85 note 2 ante.

11 For the meaning of 'relevant information' see PARA 92 note 15 ante.

12 Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 50(2). As to defences and penalties see PARAS 124-125 post.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(5) CLINICAL TRIALS/(vi) Enforcement/124. Defence of due diligence.

124. Defence of due diligence.

A person¹ does not commit an offence under the clinical trials regulations² if he took all reasonable precautions and exercised all due diligence to avoid the commission of that offence³. Where evidence is adduced which is sufficient to raise an issue with respect to that defence, the court or jury must assume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not⁴.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 I.e. the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031 (as amended). For offences under the regulations see PARAS 90-92, 95, 104-113, 117-119, 121, 123 ante.

3 Ibid reg 51(1).

4 Ibid reg 51(2). As to the burden and standard of proof in criminal trials generally see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(3) (2006 Reissue) PARA 1368 et seq.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(5) CLINICAL TRIALS/(vi) Enforcement/125. Penalties.

125. Penalties.

A person¹ guilty of an offence under the clinical trials regulations² is liable on conviction to a fine or to imprisonment, or to both³.

¹ For the meaning of 'person' see PARA 21 note 7 ante.

² I.e. the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031 (as amended). For offences under the regulations see PARAS 90-92, 95, 104-113, 117-119, 121, 123 ante.

³ Ibid reg 52. The penalty on summary conviction is a fine not exceeding the statutory maximum or imprisonment for a term not exceeding three months or both, and on conviction on indictment is a fine or imprisonment for a term not exceeding two years or both: see reg 52(a), (b). As to the statutory maximum see PARA 32 note 3 ante.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(6) TESTS ON ANIMALS/(i) In general/126. Meaning of 'medicinal test on animals'.

(6) TESTS ON ANIMALS

(i) In general

126. Meaning of 'medicinal test on animals'.

'Medicinal test on animals' means an investigation or series of investigations consisting of any of the following:

- 114 (1) the administration¹ of a medicinal product² of a particular description³ to one or more animals⁴, where there is evidence that medicinal products of that description have effects which may be beneficial to, or otherwise advantageous in relation to, that animal or those animals, and the product is administered for the purpose of ascertaining whether, or to what extent, it has those or any other effects, whether advantageous or otherwise⁵;
- 115 (2) the administration of a medicinal product to one or more animals in circumstances where there is no such evidence as is mentioned in head (1) above, and the product is administered for the purpose of ascertaining whether, or to what extent, it has any effects relevant to a medicinal purpose⁶;
- 116 (3) the administration of any substance⁷ or article, other than a medicinal product, to one or more animals for the purpose of ascertaining whether it has any effects relevant to a medicinal purpose, whether there is evidence that it has effects which may be beneficial to, or otherwise advantageous in relation to, that animal or those animals or not⁸.

1 As to the meaning of 'administer' see PARA 7 note 2 ante.

2 For the meaning of 'medicinal product' see PARA 7 ante.

3 As to the description of medicinal products see PARA 7 note 33 ante.

4 For the meaning of 'animal' see PARA 3 note 7 ante.

5 Medicines Act 1968 ss 32(6)(a), 132(1).

6 Ibid ss 32(6)(b), 132(1). For the meaning of 'a medicinal purpose' see PARA 8 ante.

7 For the meaning of 'substance' see PARA 7 note 1 ante.

8 Medicines Act 1968 ss 32(6)(c), 132(1).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(6) TESTS ON ANIMALS/(ii) Restrictions and Exemptions/127. Restrictions on medicinal tests.

(ii) Restrictions and Exemptions

127. Restrictions on medicinal tests.

Unless one or other of certain conditions is fulfilled¹, no person², in the course of a business³ carried on by him, may sell or supply any medicinal product⁴ for the purposes of a medicinal test on animals⁵, or procure the sale or supply of any medicinal product for the purposes of such a test⁶, or procure the manufacture⁷ or assembly⁸ of any medicinal product for sale or supply for the purposes of such a test⁹. The conditions are: (1) that the person is the holder¹⁰ of a product licence¹¹ which authorises the test in question¹², or he does it to the order of the holder of such a licence and, in either case, he does it in accordance with that licence¹³; or (2) that an animal test certificate¹⁴ has been issued certifying that, subject to its provisions, the licensing authority¹⁵ has consented to the test in question and that certificate is for the time being in force and the test is to be carried out in accordance with it¹⁶.

No person may import¹⁷ any medicinal product for the purposes of a medicinal test on animals unless either: (a) he is the holder of a product licence which authorises that test, or imports the product to the order of the holder of such a licence, and, in either case, he imports it in accordance with that licence¹⁸; or (b) an animal test certificate has been issued which is for the time being in force and the test is to be carried out in accordance with it¹⁹.

No person may, in the course of a business carried on by him, administer any substance or article to an animal²⁰ by way of a medicinal test on animals, or procure any substance or article to be so administered, unless either: (i) in the case of a medicinal product, there is in force a product licence which authorises that test and the product is administered in accordance with that licence or in accordance with any instructions required by the licence to be communicated to the person carrying out the test²¹; or (ii) whether the substance or article is a medicinal product or not, an animal test certificate has been issued which is for the time being in force and the substance or article is administered in accordance with it²².

1 Medicines Act 1968 s 32(1). The conditions are those set out in s 32(2): see the text and notes 10-16 infra.

2 For the meaning of 'person' see PARA 21 note 7 ante.

3 As to the meaning of 'business' see PARA 7 note 11 ante.

4 For the meaning of 'medicinal product' see PARA 7 ante.

5 Medicines Act 1968 s 32(1)(a). For the meaning of 'medicinal test on animals' see PARA 126 ante. A person is not to be treated as doing anything or procuring anything to be done for the purposes of a medicinal test on animals if the test is or is to be carried out under arrangements to which he is not a party and of which he has not been informed: s 35(7). As to offences, penalties and defences see PARA 176 et seq post.

6 Ibid s 32(1)(b).

7 As to the meaning of 'manufacture' see PARA 7 note 2 ante.

8 For the meaning of 'assembly' see PARA 6 note 8 ante.

9 Medicines Act 1968 s 32(1)(c).

10 As to references to the holder of a licence or certificate see PARA 66 note 5 ante.

11 For the meaning of 'product licence' see PARA 44 note 5 ante.

12 A product licence is to be taken to be a licence which authorises a particular medicinal test on animals if: (1) the substance or article to be administered in the test is a medicinal product of a description to which the licence relates (Medicines Act 1968 s 32(5)(a)); and (2) the uses of medicinal products of that description which are referred to in the licence are such as to include their use for the purposes of that test (s 32(5)(b)). For the meaning of 'substance' see PARA 7 note 1 ante. As to the meaning of 'administer' see PARA 7 note 2 ante. As to the description of medicinal products see PARA 7 note 33 ante.

13 Ibid s 32(2)(a). Any reference to doing anything in accordance with a licence must be construed as a reference to doing it in pursuance of such a licence and in compliance with any conditions and any limitations (whether as to area or otherwise) to which the licence is subject, and so as to not to fall within any exceptions to which it is subject; and any reference to doing anything in accordance with an animal test certificate (see note 14 infra) must be construed in a corresponding way: s 132(3) (amended by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 54, Sch 10 Pt 1 para 19(b)).

14 'Animal test certificate' means a certificate for the purposes of the Medicines Act 1968 s 32: ss 32(2)(b), 132(1). As to such certificates see PARA 130 et seq post.

15 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

16 Medicines Act 1968 s 32(2)(b). As to the incorporation of standard conditions in certificates see PARA 67 ante.

17 This prohibition brings into operation the provisions as to penalties and forfeiture in relation to improperly imported goods in the Customs and Excise Management Act 1979 ss 49, 50, 170: see CUSTOMS AND EXCISE vol 12(3) (2007 Reissue) PARAS 993-998, 1178. For the meaning of 'import' see PARA 7 note 3 ante.

18 Medicines Act 1968 s 32(3)(a).

19 Ibid s 32(3)(b).

20 For the meaning of 'animal' see PARA 3 note 7 ante.

21 Medicines Act 1968 s 32(4)(a).

22 Ibid s 32(4)(b).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(6) TESTS ON ANIMALS/(ii) Restrictions and Exemptions/128. Exemptions.

128. Exemptions.

The restrictions¹ as to the sale, supply, manufacture² and assembly³ of medicinal products⁴ for medicinal tests on animals⁵ do not apply:

- 117 (1) if the test is, or is to be, carried out in circumstances where there is no evidence that the substance⁶ or article has effects which may be beneficial to, or otherwise advantageous in relation to, the animal⁷ or animals to which it is, or is to be, administered⁸, and the arrangements for the test are such as to secure that no animal to which the substance or article is administered in the course of the test, and no carcase or part of the carcase or produce of any such animal, will be sold or supplied for human consumption⁹;
- 118 (2) to a veterinary surgeon or veterinary practitioner¹⁰ in respect of his: (a) selling or supplying, or procuring the sale or supply of, a medicinal product for the purpose of its being administered to one or more animals which are under his care¹¹; or (b) procuring the manufacture or assembly of a medicinal product where the product is specially prepared to his order for the purpose of its being administered to one or more such animals¹²; or (c) administering a substance or article to an animal which is under his care, or procuring a substance or article to be so administered¹³;
- 119 (3) to anything which is done in a registered pharmacy¹⁴ and is done there by or under the supervision of a pharmacist¹⁵ and consists of dispensing a medicinal product in accordance with a prescription given by a veterinary surgeon or veterinary practitioner¹⁶;
- 120 (4) to anything done by or under the supervision of a pharmacist which consists of procuring the preparation or dispensing of a medicinal product in accordance with a prescription given by a veterinary surgeon or veterinary practitioner or of procuring the assembly of a medicinal product¹⁷;
- 121 (5) to anything done in relation to a medicinal product where: (a) it is done by the person who, in the course of a business¹⁸ carried on by him, has manufactured or assembled the product to the order of a veterinary surgeon or veterinary practitioner who has stated that it is required for administration to an animal or herd which is under his care, or is required, at the request of another such surgeon or practitioner, for administration to an animal or herd which is under the care of that other surgeon or practitioner¹⁹; or (b) it is done by the person who, in the course of a business carried on by him, has manufactured or assembled the product to the order of a pharmacist in accordance with a prescription given by a practitioner²⁰; or (c) it consists of selling the product by way of wholesale dealing²¹ where it has been manufactured or assembled in the circumstances specified in head (5)(a) or head (5)(b) above²²;
- 122 (6) to anything done in relation to a medicinal product for the purposes of a medicinal test on animals which is to be carried out wholly outside the United Kingdom²³, unless the product falls within a class specified in an order made²⁴ by the agriculture ministers²⁵.

The restrictions²⁶ as to the administration of substances or articles to animals by way of medicinal tests do not apply in the circumstances set out in heads (1) and (2) above²⁷.

The appropriate ministers²⁸ may by order²⁹ provide that any of the above provisions³⁰ are to cease to have effect, or have effect subject to such exceptions or modifications as may be specified in the order³¹. Further exemptions to the restrictions³² may be conferred by order of the appropriate ministers³³.

1 le the restrictions imposed by the Medicines Act 1968 s 32(1): see PARA 127 ante.

2 As to the meaning of 'manufacture' see PARA 7 note 2 ante.

3 For the meaning of 'assembly' see PARA 6 note 8 ante.

4 For the meaning of 'medicinal product' see PARA 7 ante.

5 For the meaning of 'medicinal test on animals' see PARA 126 ante.

6 For the meaning of 'substance' see PARA 7 note 1 ante.

7 For the meaning of 'animal' see PARA 3 note 7 ante.

8 Medicines Act 1968 s 33(1)(a). As to the meaning of 'administer' see PARA 7 note 2 ante.

9 Ibid s 33(1)(b).

10 For the meanings of 'veterinary surgeon' and 'veterinary practitioner' see PARA 7 note 10 ante. The exemption in head (2) in the text does not have effect in relation to a veterinary surgeon or veterinary practitioner where the test is to be carried out under arrangements made by, or at the request of, another person, and (where the arrangements are made by the veterinary surgeon or veterinary practitioner and not at the request of any other person) does not have effect so as to exempt anything done in relation to a vaccine specially prepared for administration to poultry (ibid s 33(3)(a)); or in relation to any other vaccine, unless the vaccine is specially prepared for administration to the animal from which it is derived (s 33(3)(b)); or in relation to plasma or a serum, unless the plasma or serum is specially prepared for administration to one or more animals in the herd from which it is derived (s 33(3)(c)). For the meanings of 'poultry' and 'herd' see PARA 50 note 13 ante. For the meaning of 'person' see PARA 21 note 7 ante.

11 Ibid s 33(2)(a). As to persons doing anything or procuring anything to be done for the purposes of a medicinal test on animals see s 35(7); and PARA 127 note 5 ante.

12 Ibid s 33(2)(b).

13 Ibid s 33(2)(c).

14 For the meaning of 'registered pharmacy' see PARA 51 note 3 ante.

15 For the meaning of 'pharmacist' see PARA 46 note 10 ante.

16 Medicines Act 1968 s 33(4). However, the exemptions in heads (3)-(5) in the text do not apply: (1) to a vaccine specially prepared for administration to poultry (s 33(6)); or (2) to any other vaccine or any plasma or serum prepared or dispensed for administration to an animal or herd unless it is a vaccine specially prepared for administration to the animal from which it is derived (s 33(6)(a)) or it is plasma or a serum specially prepared for administration to one or more animals in the herd from which it is derived (s 33(6)(b)).

17 Ibid s 33(4). See also note 16 supra.

18 As to the meaning of 'business' see PARA 7 note 11 ante.

19 Medicines Act 1968 s 33(5)(a). See also note 16 supra.

20 Ibid s 33(5)(b). See also note 16 supra. For the meaning of 'practitioner' see PARA 7 note 10 ante.

21 As to the meaning of 'wholesale dealing' see PARA 47 note 5 ante.

22 Medicines Act 1968 s 33(5)(c). See also note 16 supra.

23 For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

24 le under the Medicines Act 1968 s 35(2)(b): see PARA 49 ante.

25 Ibid s 35(4). For the meaning of 'the agriculture ministers' see PARA 3 note 5 ante.

26 Ie the restrictions imposed by ibid s 32(4): see PARA 127 ante.

27 Ibid s 33(1), (2).

28 For the meaning of 'the appropriate ministers' see PARA 3 ante.

29 As to the making of orders see PARA 5 ante.

30 Ie any of the provisions of the Medicines Act 1968 ss 33, 35(4).

31 Ibid s 35(10). No such order may be made unless a draft of the order has been laid before Parliament and approved by a resolution of each House of Parliament: s 35(11). As to the laying of documents before Parliament see PARLIAMENT vol 34 (Reissue) PARA 941. As to the order that has been made see the Medicines (Exemption from Licences) (Medicinal Tests on Animals) Order 1977, SI 1977/161.

32 Ie the restrictions set out in the Medicines Act 1968 s 32: see PARA 127 ante.

33 See ibid s 35(8)(b). Any exemption conferred by such an order may be conferred subject to such conditions or limitations as may be specified in the order: s 35(9). As to the orders made see the Medicines (Exemption from Licences) (Special Cases and Miscellaneous Provisions) Order 1972, SI 1972/1200 (amended by SI 1974/498; SI 1977/161; SI 1989/2323; SI 1994/2987; SI 2004/1031); and the Medicines (Exemption from Licences) (Medicinal Tests on Animals) Order 1977, SI 1977/161.

UPDATE

128 Exemptions

NOTES 31, 33--SI 1972/1200 amended, SI 1977/161 revoked: SI 2005/2745.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(6) TESTS ON ANIMALS/(ii) Restrictions and Exemptions/129. Restrictions on subsequent sale or supply.

129. Restrictions on subsequent sale or supply.

No person¹, in the course of a business² carried on by him, may sell or supply for human consumption an animal³ to which in the course of that business a substance⁴ or article has been administered⁵ by way of a test⁶ or the carcase of any part of it or any produce of such an animal⁷, unless at the time when the substance or article was administered there was in force an animal test certificate⁸ issued in respect of that test⁹, and all the provisions of that certificate relating to the carrying out of the test and the disposal of the animal or its carcase or produce are, and have at all material times been, complied with¹⁰.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 As to the meaning of 'business' see PARA 7 note 11 ante.

3 For the meaning of 'animal' see PARA 3 note 7 ante.

4 For the meaning of 'substance' see PARA 7 note 1 ante.

5 As to the meaning of 'administer' see PARA 7 note 2 ante.

6 Ie any medicinal test on animals which is carried out in the course of the business of the person who has manufactured the substance or article, or is carried out on his behalf in the course of the business of a laboratory or research establishment carried on by another person, and, in either case, is so carried out on one or more animals kept in the course of the business of the person carrying out the test: Medicines Act 1968 s 34(2). For the meaning of 'medicinal test on animals' see PARA 126 ante. As to the meaning of 'manufacture' see PARA 7 note 2 ante.

7 Ibid s 34(1). Contravention of any of the provisions of s 34 is an offence: see s 45(1); and PARA 176 post.

8 For the meaning of 'animal test certificate' see PARA 127 note 14 ante.

9 Medicines Act 1968 s 34(1)(a).

10 Ibid s 34(1)(b).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(6) TESTS ON ANIMALS/(iii) Animal Test Certificates/130. Application for certificate.

(iii) Animal Test Certificates

130. Application for certificate.

Any application¹ for an animal test certificate must be made to the licensing authority² in such form and manner, and must contain or be accompanied by such information, documents, samples and other material, as may be prescribed³. In dealing with an application, the authority must have regard in particular to any evidence available to it as to any risks involved in the proposed medicinal test on animals⁴.

The provisions relating to the grant or refusal of licences⁵ and the procedure to be adopted in dealing with applications for licences⁶ apply also to the grant or refusal of applications for animal test certificates⁷. Standard provisions for certificates may be prescribed⁸.

1 Unless the application otherwise expressly provides, every application for the grant or renewal of an animal test certificate is to be taken to be an application for the grant or renewal of the certificate for the full period of two years referred to in PARA 131 post: Medicines Act 1968 s 38(6). Any reference to the grant or renewal of an animal test certificate otherwise than in accordance with the application must be construed accordingly: see s 38(6). For the meaning of 'animal test certificate' see PARA 127 note 14 ante.

2 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

3 Medicines Act 1968 s 36(1). For the meaning of 'prescribed' see PARA 56 note 3 ante. The following regulations have been made: the Medicines (Renewal Applications for Licences and Certificates) Regulations 1974, SI 1974/832 (amended by SI 1977/180; SI 1982/1789; SI 1992/755; SI 1993/1227; SI 2004/1031); the Medicines (Applications for Product Licences and Clinical Trial and Animal Test Certificates) Amendment Regulations 1977, SI 1977/1051; the Medicines (Contact Lens Fluids and Other Substances) (Advertising and Miscellaneous Amendments) Regulations 1979, SI 1979/1760 (amended by SI 2005/848); and the Medicines (Renewal Applications for Licences and Certificates) Amendment Regulations 1982, SI 1982/1789. As to the power to require the applicant to furnish information in relation to an application see PARA 57 ante. As to the right of an authorised person to enter premises to verify statements contained in an application see PARA 169 post; and as to the power to inspect and take samples for that purpose see PARA 170 post. As to the fees payable on applications see the Medicines (Products for Human Use--Fees) Regulations 1995, SI 1995/1116 (amended by SI 1996/683; SI 1998/574; SI 1999/566; SI 2000/592; SI 2000/3031; SI 2001/795; SI 2002/236; SI 2002/542; SI 2003/625; SI 2003/2321; SI 2004/666; SI 2004/1157; SI 2005/1124); and the Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750 (amended by SI 2004/3081).

4 Medicines Act 1968 s 36(2). For the meaning of 'medicinal test on animals' see PARA 126 ante.

5 *Ibid* s 20 (as amended): see PARAS 61, 65 ante.

6 *Ibid* ss 21, 22 (both as substituted) and s 22A (as added): see PARAS 62-64 ante.

7 *Ibid* s 36(3) (amended by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 8, Sch 1 para 6).

8 See the Medicines Act 1968 s 47; and PARA 67 ante.

UPDATE

130 Application for certificate

NOTE 3--SI 1974/832 revoked, in relation to manufacturer's licences and wholesale dealer's licences in so far as such licences relate to relevant medicinal products, by the

Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005, SI 2005/2789. For these purposes 'relevant medicinal product' means a medicinal product for human use to which the provisions of the Directive apply; the 'Directive' means EC Council EC Parliament and Council Directive 2001/83 on the Community code relating to medicinal products for human use: SI 2005/2789 reg 1. SI 1979/1760 further amended: SI 2007/3101. SI 1995/1116 replaced: see now the Medicines (Products for Human Use) (Fees) Regulations 2009, SI 2009/389 (amended by SI 2009/3222). SI 2004/2750 revoked: SI 2005/2745.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(6) TESTS ON ANIMALS/(iii) Animal Test Certificates/131. Duration and renewal of certificates.

131. Duration and renewal of certificates.

Unless previously renewed or revoked¹, every animal test certificate² expires at the end of the period of two years from the date on which it was issued or the date as from which it was last renewed, or at the end of such shorter period from that date as may be specified in the certificate as issued or last renewed³.

Any such certificate which has not been revoked may be renewed by the licensing authority⁴ on the application⁵ of the holder⁶ of the certificate for a further period of two years from the date on which it would otherwise expire or such shorter period as the authority may determine⁷. On an application for renewal⁸ the authority may renew the certificate, with or without modifications⁹, or may issue a new certificate containing such provisions as it considers appropriate¹⁰ or, if, having regard to the provisions of the Medicines Act 1968, it considers it necessary or expedient to do so, may refuse to renew the certificate or to issue a new certificate¹¹. Where an application for the renewal of a certificate has been duly made, the certificate does not cease to be in force before the authority has determined the application¹², or during any period in which the operation of the decision of the licensing authority is, by an interim order of the High Court¹³, suspended¹⁴.

1 As to the revocation of certificates see PARA 132 post.

2 For the meaning of 'animal test certificate' see PARA 127 note 14 ante.

3 Medicines Act 1968 s 38(1). As to applications for certificates see PARA 130 ante. As to the suspension and variation of certificates see PARA 132 post.

4 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

5 See the Medicines Act 1968 s 38(6); and PARA 130 note 1 ante. The provisions of s 36(1), (2) (see PARA 130 ante) have effect in relation to renewal applications as they do in relation to applications for the issue of certificates: s 38(3). As to the form and manner of renewal applications and the particulars and samples which must accompany them see the Medicines (Renewal Applications for Licences and Certificates) Regulations 1974, SI 1974/832 (amended by SI 1977/180; SI 1982/1789; SI 1992/755; SI 1993/1227; SI 2004/1031).

6 As to references to the holder of a certificate see PARA 66 note 5 ante.

7 Medicines Act 1968 s 38(2).

8 The procedure specified by *ibid* s 20(2)-(5) (as amended), ss 21-22 (as substituted) and s 22A (as added) (see PARAS 61, 62-65 ante) applies with appropriate modifications to renewal applications: see s 38(5), (6) (amended by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 8, Sch 1 para 7).

9 Medicines Act 1968 s 38(4)(a).

10 *Ibid* s 38(4)(b).

11 *Ibid* s 38(4)(c). As to challenges to the validity of the authority's decisions see s 107; and PARA 79 ante.

12 *Ibid* s 38(7)(a).

13 *Ie* an order made under *ibid* s 107(3)(a): see PARA 79 ante.

14 See *ibid* s 38(7)(b).

UPDATE

131 Duration and renewal of certificates

NOTE 5--SI 1974/832 revoked, in relation to manufacturer's licences and wholesale dealer's licences in so far as such licences relate to relevant medicinal products, by the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005, SI 2005/2789. For these purposes 'relevant medicinal product' means a medicinal product for human use to which the provisions of the Directive apply; the 'Directive' means EC Council EC Parliament and Council Directive 2001/83 on the Community code relating to medicinal products for human use: SI 2005/2789 reg 1.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(6) TESTS ON ANIMALS/(iii) Animal Test Certificates/132. Suspension, revocation or variation of certificates.

132. Suspension, revocation or variation of certificates.

The licensing authority¹ may suspend, for such period as it may determine, an animal test certificate², or it may revoke it or vary its provisions³, on one or more of the following grounds:

- 123 (1) that the matters stated in the application on which the certificate was issued were false or incomplete in a material particular⁴;
- 124 (2) that any of the provisions of the certificate has to a material extent been contravened⁵;
- 125 (3) that medicinal products⁶ of any description⁷ to which the certificate relates, as sold, supplied, exported⁸, imported⁹, manufactured¹⁰ or assembled¹¹ for the purposes of the medicinal test on animals¹² to which it relates, fail to a material extent to correspond to the characteristics by reference to which the certificate was issued¹³;
- 126 (4) that the holder¹⁴ of the certificate has failed without reasonable excuse to comply with a requirement to furnish information¹⁵ with respect to any substances¹⁶ or articles to which the certificate relates¹⁷;
- 127 (5) that any substances or articles can no longer be regarded as substances or articles which can safely¹⁸ be administered¹⁹ for the purposes of the medicinal test on animals to which the certificate relates²⁰;
- 128 (6) that the specification and standards to which any substances or articles are manufactured can no longer be regarded as satisfactory²¹.

On the application of the holder of a certificate, the licensing authority may vary the provisions of the certificate in accordance with any proposals contained in the application, if it is satisfied that the variation will not adversely affect the safety, quality or efficacy of medicinal products of any description to which the certificate relates²².

1 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

2 For the meaning of 'animal test certificate' see PARA 127 note 14 ante.

3 Medicines Act 1968 s 39(1). The provisions of s 29, Sch 2 (see PARAS 73-77 ante), specifying the procedure to be followed where the authority proposes to suspend, revoke or vary a licence, apply also to the suspension, revocation or variation of a certificate under s 39, but as if the reference in Sch 2 para 1 to s 28 (3)(g) or (h) were a reference to s 39(2)(e) or (f): see s 39(3). As to challenges to the validity of the authority's decisions see s 107; and PARA 79 ante.

4 Ibid s 39(2)(a). As to applications for a certificate see PARA 130 ante.

5 Ibid s 39(2)(b). As to standard provisions for certificates see PARA 67 ante.

6 For the meaning of 'medicinal product' see PARA 7 ante.

7 As to the description of medicinal products see PARA 7 note 33 ante.

8 For the meaning of 'export' see PARA 7 note 4 ante.

9 For the meaning of 'import' see PARA 7 note 3 ante.

10 As to the meaning of 'manufacture' see PARA 7 note 2 ante.

- 11 For the meaning of 'assemble' see PARA 6 note 8 ante.
- 12 For the meaning of 'medicinal test on animals' see PARA 126 ante.
- 13 Medicines Act 1968 s 39(2)(c).
- 14 As to references to the holder of a certificate see PARA 66 note 5 ante.
- 15 le under the Medicines Act 1968 s 44(2); see PARA 70 ante.
- 16 For the meaning of 'substance' see PARA 7 note 1 ante.
- 17 Medicines Act 1968 s 39(2)(d).
- 18 As to considerations of safety see PARA 15 note 10 ante.
- 19 As to the meaning of 'administer' see PARA 7 note 2 ante.
- 20 Medicines Act 1968 s 39(2)(e).
- 21 Ibid s 39(2)(f).
- 22 Ibid s 39(4).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(7) SALE AND SUPPLY OF MEDICINAL PRODUCTS/(i) Products on a General Sale List/A. RESTRICTIONS/133. General sale lists.

(7) SALE AND SUPPLY OF MEDICINAL PRODUCTS

(i) Products on a General Sale List

A. RESTRICTIONS

133. General sale lists.

The appropriate ministers¹ may specify by order² descriptions or classes of medicinal products³ as being products which in their opinion can with reasonable safety⁴ be sold or supplied otherwise than by, or under the supervision of, a pharmacist⁵. Medicinal products of a description or falling within a class so specified are known as 'medicinal products on a general sale list'⁶.

Any such order may designate any description or class of medicinal products specified in it as being medicinal products which, in the opinion of the appropriate ministers, can with reasonable safety be sold by means of automatic machines⁷. Medicinal products of a description or falling within a class so designated are known as 'medicinal products in the automatic machines section of a general sale list'⁸.

1 For the meaning of 'the appropriate ministers' see PARA 3 ante.

2 As to the making of orders see PARA 5 ante.

3 For the meaning of 'medicinal product' see PARA 7 ante. As to the description of medicinal products see PARA 7 note 33 ante.

4 As to considerations of safety see PARA 15 note 10 ante.

5 Medicines Act 1968 s 51(1). For the meaning of 'pharmacist' see PARA 46 note 10 ante. As to the orders that have been made see the Medicines (Products other than Veterinary Drugs) (General Sale List) Order 1984, SI 1984/769 (amended by SI 1985/1540; SI 1987/910; SI 1989/969; SI 1990/1129; SI 1992/1535; SI 1994/2410; SI 1995/3216; SI 1997/2043; SI 1998/2170; SI 1999/852; SI 1999/2535; SI 2000/1092; SI 2000/2526; SI 2001/2068; SI 2001/4111; SI 2002/933; SI 2005/2750); the Medicines (Registered Homoeopathic Veterinary Medicinal Products) (General Sale List) Order 1997, SI 1997/1349; and the Medicines (Veterinary Drugs) (General Sale List) Order 2001, SI 2001/1645. A national prohibition on the sale by mail order of medicinal products which may be sold generally and are not limited to sale only in pharmacies is not justified: Case C-322/01 *Deutscher Apothekerverband eV v 0800 DocMorris NV* [2003] ECR I-14887, 81 BMLR 33, [2003] All ER (D) 213 (Dec), ECJ.

6 See the Medicines Act 1968 s 51(2).

7 Ibid s 51(3). See the Medicines (Products other than Veterinary Drugs) (General Sale List) Order 1984, SI 1984/769 (as amended); and note 5 supra. As to the sale of medicinal products from automatic machines see PARA 136 post.

8 See the Medicines Act 1968 s 51(3).

UPDATE

133 General sale lists

NOTE 5--SI 1997/1349, SI 2001/1645 revoked: SI 2005/2745.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(7) SALE AND SUPPLY OF MEDICINAL PRODUCTS/(i) Products on a General Sale List/A. RESTRICTIONS/134. Sale or supply of products not on general sale list.

134. Sale or supply of products not on general sale list.

Subject to certain exemptions¹, no person², in the course of a business³ carried on by him, may sell by retail⁴, offer or expose for sale by retail or supply in circumstances corresponding to retail sale⁵, any medicinal product⁶ which is not a medicinal product on a general sale list⁷ unless, in respect of that business, that person is a person lawfully conducting a retail pharmacy business⁸, the product is sold, offered or exposed for sale, or supplied, on premises which are a registered pharmacy⁹ and that person or, if the transaction is carried out on his behalf by another person, then that other person, is or acts under the supervision of a pharmacist¹⁰. Any person who contravenes¹¹ this provision is guilty of an offence¹².

1 le any exemption conferred by or under the Medicines Act 1968 Pt III (ss 51-68) (as amended): see PARA 137 et seq post. See, in particular, PARA 139 note 5 post.

2 For the meaning of 'person' see PARA 21 note 7 ante.

3 As to the meaning of 'business' see PARA 7 note 11 ante. As to the carrying on of a business by the Secretary of State see PARA 47 note 5 ante.

4 As to references to retail sale and selling by retail see PARA 7 note 12 ante.

5 As to references to supplying anything in circumstances corresponding to retail sale see PARA 7 note 13 ante.

6 For the meaning of 'medicinal product' see PARA 7 ante.

7 For the meaning of 'medicinal products on a general sale list' see PARA 133 ante.

8 Medicines Act 1968 s 52(a). For the meaning of 'retail pharmacy business' see PARA 51 note 3 ante.

9 Ibid s 52(b). For the meaning of 'registered pharmacy' see PARA 51 note 3 ante.

10 Ibid s 52(c). For the meaning of 'pharmacist' see PARA 46 note 10 ante. The prohibition imposed by s 52 applies only to acts done on or after 1 February 1978: s 52; Medicines (Pharmacy and General Sale) (Appointed Day) Order 1977, SI 1977/2126. A national prohibition on the sale by mail order of medicinal products which may be sold only in pharmacies is justified in so far as the prohibition covers medicinal products subject to prescription, but an absolute prohibition on the sale by mail order of medicinal products which are not subject to prescription is not justified: Case C-322/01 *Deutscher Apothekerverband eV v 0800 DocMorris NV* [2003] ECR I-14887, 81 BMLR 33, [2003] All ER (D) 213 (Dec), ECJ. See also Case 215/87 *Schumacher v Hauptzollamt Frankfurt am Main-Ost* [1989] ECR 617, [1990] 2 CMLR 465, ECJ.

11 For the meaning of 'contravene' see PARA 6 note 21 ante.

12 Medicines Act 1968 s 67(2). Such a person is liable on summary conviction to a fine not exceeding the prescribed sum (s 67(4)(a) (amended by virtue of the Magistrates' Courts Act 1980 s 32(2)) or, on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both (Medicines Act 1968 s 67(2), (4)(b)). As to the prescribed sum see PARA 32 note 3 ante. Certain presumptions apply to such an offence: see PARA 184 post. As to enforcement, prosecutions, defences and related matters see PARA 176 et seq post.

UPDATE

134 Sale or supply of products not on general sale list

TEXT AND NOTES 8-10--The following provisions are not yet in force. 1968 Act s 52 now 1968 Act s 52(1): Health Act 2006 s 26(2)(a). The health ministers may make regulations prescribing conditions which must be complied with if a transaction mentioned in the 1968 Act s 52(1)(c) is to be considered for the purposes of s 52 as done under the supervision of a pharmacist: s 52(2) (added by Health Act 2006 s 26(2)(b)). Conditions prescribed under the 1968 Act s 52(2) may relate to supervision in the case where the pharmacist is not on the premises, and in that case the transaction is not to be so considered if no such conditions are prescribed: s 52(3) (as so added). In any case, compliance with any applicable conditions is sufficient for the transaction to be so considered: s 52(4) (as so added).

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135. Sale or supply of products on general sale list.

Subject to certain exemptions¹, no person², in the course of a business³ carried on by him, may sell by retail⁴ or offer or expose for sale by retail, or supply in circumstances corresponding to retail sale⁵, any medicinal product⁶ on a general sale list⁷ elsewhere than at a registered pharmacy⁸ unless the following conditions are fulfilled⁹:

- 129 (1) the place at which the medicinal product is sold, offered, exposed or supplied must be premises of which the person carrying on the business in question is the occupier and which he is able to close so as to exclude the public¹⁰, unless either the product is sold, offered, exposed for sale or supplied by means of an automatic machine and is a medicinal product in the automatic machines section of a general sale list¹¹, or the product is a veterinary drug¹²;
- 130 (2) the medicinal product must have been made up for sale in a container¹³ elsewhere than at the place at which it is sold, offered, exposed for sale or supplied and the container must not have been opened since the product was made up for sale in it¹⁴; and
- 131 (3) the business, so far as concerns the sale or supply of medicinal products, must be carried on in accordance with such conditions, if any, as may be prescribed¹⁵.

Any person who contravenes¹⁶ these provisions is guilty of an offence¹⁷.

¹ ie any exemption conferred by or under the Medicines Act 1968 Pt III (ss 51-68) (as amended): see PARA 137 et seq post. See, in particular, PARA 139 note 5 post.

² For the meaning of 'person' see PARA 21 note 7 ante.

³ As to the meaning of 'business' see PARA 7 note 11 ante.

⁴ As to references to retail sale and selling by retail see PARA 7 note 12 ante.

⁵ As to references to supplying anything in circumstances corresponding to retail sale see PARA 7 note 13 ante.

⁶ For the meaning of 'medicinal product' see PARA 7 ante.

⁷ For the meaning of 'medicinal products on a general sale list' see PARA 133 ante.

⁸ For the meaning of 'registered pharmacy' see PARA 51 note 3 ante.

⁹ Medicines Act 1968 s 53(1). The prohibition imposed by s 53 applies only to acts done on or after 1 February 1978: s 53(1); Medicines (Pharmacy and General Sale) (Appointed Day) Order 1977, SI 1977/2126.

¹⁰ Medicines Act 1968 s 53(2).

¹¹ Ibid s 53(2)(a). For the meaning of 'medicinal products in the automatic machines section of a general sale list' see PARA 133 ante. As to the sale of medicinal products from automatic machines see PARA 136 post.

¹² Ibid s 53(2)(b). For the meaning of 'veterinary drug' see PARA 3 note 7 ante.

¹³ For the meaning of 'container' see PARA 152 note 4 post.

14 Medicines Act 1968 s 53(3).

15 Ibid s 53(4). For the meaning of 'prescribed' see PARA 56 note 3 ante. As to the making of regulations see PARA 5 ante. For regulations made under this provision see the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980, SI 1980/1923 (amended by SI 1982/28; SI 1990/1124; SI 1990/2487; SI 1992/2938; SI 1994/2411; SI 1994/3142; SI 1994/3144; SI 1995/3215; SI 1997/1831; SI 1997/2045; SI 1998/1045; SI 1999/644; SI 1999/2510; SI 2000/7; SI 2000/1070; SI 2000/1918; SI 2000/2494; SI 2001/3849; SI 2002/2469; SI 2003/698; SI 2004/696; SI 2004/1771; SI 2005/764; SI 2005/1520; SI 2005/2750).

16 For the meaning of 'contravene' see PARA 6 note 21 ante.

17 Medicines Act 1968 s 67(5) (amended by virtue of the Criminal Justice Act 1982 ss 38, 46). Such a person is liable on summary conviction to a fine not exceeding level 3 on the standard scale: see the Medicines Act 1968 s 67(5) (as so amended). As to the standard scale see PARA 6 note 22 ante. Certain presumptions apply to such an offence: see PARA 184 post. As to enforcement, prosecutions, defences and related matters see PARA 176 et seq post.

UPDATE

135 Sale or supply of products on general sale list

NOTE 15--SI 1980/1923 further amended: see PARA 6 NOTE 2.

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136. Sale of medicinal products from automatic machines.

No person¹ may sell, or offer or expose for sale, any medicinal product² by means of an automatic machine unless it is a medicinal product in the automatic machines section of a general sale list³.

The appropriate ministers⁴ may by order⁵ provide that no person is to sell or offer or expose for sale by means of an automatic machine any medicinal product to which the order applies unless the container⁶ in which it is sold, or offered or exposed for sale, complies with such restrictions as to the quantity of the medicinal product or the number of medicinal products which it contains as may be specified in the order⁷.

Any person who contravenes⁸ the provisions as to automatic machines or the provisions of such an order is guilty of an offence⁹.

Every automatic machine which is for use for the sale of any medicinal product in the automatic machines section of a general sale list must be located in premises which the occupier is able to close so as to exclude the public¹⁰. Any person who contravenes this regulation is guilty of an offence¹¹.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 For the meaning of 'medicinal product' see PARA 7 ante.

3 Medicines Act 1968 s 54(1). For the meaning of 'medicinal products in the automatic machines section of a general sale list' see PARA 133 ante. The prohibition imposed by s 54 applies only to acts done on or after 1 February 1978: s 54(1); Medicines (Pharmacy and General Sale) (Appointed Day) Order 1977, SI 1977/2126.

4 For the meaning of 'the appropriate ministers' see PARA 3 ante.

5 As to the making of orders see PARA 5 ante.

6 For the meaning of 'container' see PARA 152 note 4 post.

7 Medicines Act 1968 s 54(2). Such an order may be made either in respect of medicinal products generally or in respect of medicinal products of a particular description or falling within a particular specified class: s 54(3). As to the description of medicinal products see PARA 7 note 33 ante. At the date at which this volume states the law, no such order had been made.

8 For the meaning of 'contravene' see PARA 6 note 21 ante.

9 Medicines Act 1968 s 67(5) (amended by virtue of the Criminal Justice Act 1982 ss 38, 46). Such a person is liable on summary conviction to a fine not exceeding level 3 on the standard scale: see the Medicines Act 1968 s 67(5) (as so amended). As to the standard scale see PARA 6 note 22 ante. As to enforcement, prosecutions, defences and related matters see PARA 176 et seq post.

10 Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980, SI 1980/1923, reg 4. This provision is made under the Medicines Act 1968 s 66(1)(b) (see PARA 6 ante). As to the information to be displayed on automatic machines see PARA 156 post.

11 Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980, SI 1980/1923, reg 9. Such a person is liable on summary conviction to a fine not exceeding £400: see reg 9.

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B. EXEMPTIONS

137. Exemptions for practitioners, nurses and midwives.

The restrictions on the sale or supply of medicinal products¹ not on a general sale list² and of medicinal products on a general sale list³ do not apply to the sale, offer for sale or supply of a medicinal product: (1) by a doctor⁴ or dentist⁵ to a patient of his or to a person under whose care such a patient is⁶; or (2) where the product is sold, offered for sale or supplied in the course of the business⁷ of a hospital⁸ or health centre⁹ for the purpose of being administered¹⁰ in accordance with the directions of a doctor or dentist¹¹; or (3) by a veterinary surgeon or veterinary practitioner¹² for administration by him or under his direction to an animal¹³ or herd¹⁴ under his care¹⁵.

Furthermore, those restrictions¹⁶ do not apply to the sale or supply of a medicinal product in the course of professional practice by a registered nurse or registered midwife¹⁷, or where a medicinal product is delivered or administered by such a midwife on being supplied in pursuance of arrangements made by the Secretary of State¹⁸, provided in each case that the medicinal product is of a description or falls within a class specified in an order made by the health ministers¹⁹ for the purpose²⁰.

1 For the meaning of 'medicinal product' see PARA 7 ante.

2 I.e. the restrictions imposed by the Medicines Act 1968 s 52: see PARA 134 ante. For the meaning of 'medicinal products on a general sale list' see PARA 133 ante.

3 I.e. the restrictions imposed by *ibid* s 53: see PARA 135 ante.

4 For the meaning of 'doctor' see PARA 7 note 10 ante.

5 For the meaning of 'dentist' see PARA 7 note 10 ante.

6 Medicines Act 1968 s 55(1)(a). It is not necessary that a doctor personally hand over the medicines to patients; he may delegate to another, who is neither a doctor nor a pharmacist, the supply of medicine to his patients: *R v Family Health Services Appeal Authority, ex p Elmfield Drugs Ltd* (1998) 46 BMLR 191, [1998] All ER (D) 365, CA.

7 As to the meaning of 'business' see PARA 7 note 11 ante.

8 For the meaning of 'hospital' see PARA 86 note 2 ante.

9 For the meaning of 'health centre' see PARA 86 note 2 ante.

10 I.e. whether in the hospital or health centre or elsewhere: Medicines Act 1968 s 55(1)(b). As to the meaning of 'administer' see PARA 7 note 2 ante.

11 *Ibid* s 55(1)(b). The appropriate ministers may by order provide that the provisions of s 55(1)(b), (2) (see the text to notes 16-20 *infra*) are to cease to have effect, or are to have effect subject to such exceptions or modifications as may be specified in the order: s 57(3). No such order may be made unless a draft of the order has been laid before Parliament and approved by a resolution of each House of Parliament: s 57(4). For the meaning of 'the appropriate ministers' see PARA 3 ante. As to the laying of documents before Parliament see PARLIAMENT vol 34 (Reissue) PARA 941. As to the making of orders see PARA 5 ante. At the date at which this volume states the law no such order had been made.

- 12 For the meanings of 'veterinary surgeon' and 'veterinary practitioner' see PARA 7 note 10 ante.
- 13 For the meaning of 'animal' see PARA 3 note 7 ante.
- 14 For the meaning of 'herd' see PARA 50 note 13 ante.
- 15 Medicines Act 1968 s 55(3).
- 16 Ie the restrictions imposed by ibid ss 52, 53: see PARAS 134-135 ante.
- 17 Ibid s 55(2)(a), (b) (amended by the Health Act 1999 (Consequential Amendments) (Nursing and Midwifery) Order 2004, SI 2004/1771, art 3, Schedule Pt 1 para 10(b)). As to nurses and midwives see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 691 et seq. As to the power of nurses, midwives and health visitors to prescribe medicinal products for the purposes of the Medicines Act 1968 see PARA 140 post.
- 18 Ibid s 55(2)(b) (amended by the National Health Service Reorganisation Act 1973 s 57(1), Sch 4 para 128(1)). As to the Secretary of State see PARA 3 note 3 ante.
- 19 For the meaning of 'the health ministers' see PARA 3 note 4 ante.
- 20 Medicines Act 1968 s 55(2)(a), (b). See also note 11 supra. As to the order that has been made see the Medicines (Pharmacy and General Sale--Exemption) Order 1980, SI 1980/1924 (amended by SI 1982/27; SI 1989/1852; SI 1994/2409; SI 1994/3142; SI 1944/3144; SI 1997/1350; SI 1998/107; SI 1998/2368; SI 2000/1919; SI 2002/880; SI 2002/2469; SI 2003/697; SI 2003/1590; SI 2004/1; SI 2004/696; SI 2004/865; SI 2004/1016; SI 2004/1190; SI 2004/1771; SI 2004/2261; SI 2004/3038; SI 2005/766; SI 2005/848; SI 2005/1507; SI 2005/2750; SI 2005/2759).

UPDATE

137 Exemptions for practitioners, nurses and midwives

NOTE 20--SI 1980/1924 further amended: SI 2005/2745, SI 2005/3324, SI 2006/562, SI 2006/915, SI 2006/2807, SI 2007/289, SI 2007/2178, SI 2008/1161, SI 2009/1165, SI 2009/3062.

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138. Exemptions in respect of herbal remedies.

The restrictions on the sale or supply of medicinal products¹ not on a general sale list² and of medicinal products on a general sale list³ do not apply⁴ to the sale or offer or exposure for sale or the supply in circumstances corresponding to retail sale⁵ of a herbal remedy⁶ where the processes to which the plant⁷ or plants are subjected consist of drying, crushing or comminuting⁸, but not any other process, at premises of which the person⁹ carrying on the business¹⁰ in question is the occupier and which he is able to close so as to exclude the public¹¹.

Nor do those restrictions apply¹² to the sale or supply of a herbal remedy where the person selling or supplying it does so for administration¹³ to a particular person after being requested by or on behalf of that person and in that person's presence to use his own judgment as to the treatment¹⁴ required¹⁵.

The appropriate ministers¹⁶ may by order¹⁷ provide that these exemptions are not to have effect in relation to specified descriptions or classes of herbal remedies¹⁸.

1 For the meaning of 'medicinal product' see PARA 7 ante.

2 I.e. the restrictions imposed by the Medicines Act 1968 s 52: see PARA 134 ante. For the meaning of 'medicinal products on a general sale list' see PARA 133 ante.

3 I.e. the restrictions imposed by ibid s 53: see PARA 135 ante.

4 See, however, ibid s 56(3); and the text and notes 16-18 infra.

5 As to references to supplying anything in circumstances corresponding to retail sale see PARA 7 note 13 ante.

6 For the meaning of 'herbal remedy' see PARA 7 note 14 ante.

7 As to the meaning of 'plant' see PARA 7 note 14 ante.

8 I.e. with or without any subsequent process of tableting, pill-making, compressing or diluting with water: Medicines Act 1968 s 56(1).

9 For the meaning of 'person' see PARA 21 note 7 ante.

10 As to the meaning of 'business' see PARA 7 note 11 ante.

11 Medicines Act 1968 s 56(1). Section 56 does not apply in relation to traditional herbal medicinal products (see PARA 230 post): Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, SI 2005/2750, reg 10(3).

12 See, however, the Medicines Act 1968 s 56(3); and the text and notes 16-18 infra.

13 As to the meaning of 'administer' see PARA 7 note 2 ante.

14 For the meaning of 'treatment' see PARA 8 note 1 ante.

15 Medicines Act 1968 s 56(2).

16 For the meaning of 'the appropriate ministers' see PARA 3 ante.

17 As to the making of orders see PARA 5 ante.

18 Medicines Act 1968 s 56(3). As to the order that has been made see the Medicines (Retail Sale or Supply of Herbal Remedies) Order 1977, SI 1977/2130 (amended by SI 2005/2750).

UPDATE

138 Exemptions in respect of herbal remedies

NOTE 18--SI 1977/2130 further amended: SI 2005/2745, SI 2005/2789, SI 2006/395.

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139. Power to extend or modify exemptions.

The appropriate ministers¹ may by order² confer additional exemptions from the restrictions as to the sale or supply of medicinal products³ not on a general sale list⁴ and of medicinal products on a general sale list⁵. These additional exemptions may be conferred subject to specified conditions or limitations⁶.

An order providing for the exemption⁷ of the sale by retail⁸, or the offer or exposure for sale by retail or the supply in circumstances corresponding to retail sale⁹ of veterinary drugs¹⁰ by any persons¹¹ may, as a condition of the exemption, require those persons to be entered for the time being in a register of merchants in veterinary drugs kept by the registrar¹², and may impose such conditions as the appropriate ministers think fit in respect of the inclusion or retention of persons in the register, including conditions requiring the payment to the registrar of fees of such amounts as the appropriate ministers may with the consent of the Treasury determine¹³.

1 For the meaning of 'the appropriate ministers' see PARA 3 ante.

2 As to the making of orders see PARA 5 ante.

3 For the meaning of 'medicinal product' see PARA 7 ante.

4 Ie the restrictions imposed by the Medicines Act 1968 s 52: see PARA 134 ante. For the meaning of 'medicinal products on a general sale list' see PARA 133 ante.

5 See *ibid* s 57(1). As to the restrictions imposed in relation to products on a general sale list see s 53; and PARA 135 ante. As to the orders that have been made under s 57(1) see the Medicines (Retail Sale or Supply of Herbal Remedies) Order 1977, SI 1977/2130 (as amended) (see PARA 138 note 18 ante); the Medicines (Collection and Delivery Arrangements--Exemption) Order 1978, SI 1978/1421; the Medicines (Pharmacy and General Sale--Exemption) Order 1980, SI 1980/1924 (as amended) (see PARA 137 note 20 ante); the Medicines (Exemptions for Merchants in Veterinary Drugs) Order 1998, SI 1998/1044 (amended by SI 2000/2686); and the Medicines (Vaccination against Foot-and-Mouth Disease) Order 2004, SI 2004/2779. As to the power of the appropriate ministers to provide, by order, that the Medicines Act 1968 s 55(1)(b), (2) are either to cease to have effect or to have effect subject to specified exceptions or modifications see PARA 137 ante.

6 *Ibid* s 57(2).

7 Ie from *ibid* s 52: see PARA 134 ante.

8 As to references to retail sale and selling by retail see PARA 7 note 12 ante.

9 As to references to supplying anything in circumstances corresponding to retail sale see PARA 7 note 13 ante.

10 For the meaning of 'veterinary drug' see PARA 3 note 7 ante.

11 For the meaning of 'person' see PARA 21 note 7 ante.

12 Medicines Act 1968 s 57(2A)(a) (s 57(2A)-(2D) added by the Animal Health and Welfare Act 1984 s 14). 'The registrar' means the person appointed under the Pharmacy Act 1954 s 1 as registrar for the purposes of that Act: Medicines Act 1968 s 57(2D) (as so added). As to such person see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 884.

13 *Ibid* s 57(2A)(b) (as added: see note 12 supra). As to the Treasury see CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARAS 512-517. In determining fees the appropriate ministers may consider: (1) the costs of the Pharmaceutical Society in relation to the enforcement of s 52 or of regulations, in so far as they are

concerned with veterinary drugs; and (2) the costs of any other person for the purpose of improving or maintaining standards among those engaged in the retail sale, or supply in corresponding circumstances, of veterinary drugs: s 57(2B) (as so added). Fees received for registration or retention in a register may be applied, if and to the extent that the appropriate ministers determine, towards meeting costs under head (2) supra; otherwise they must be applicable for the purposes of the Pharmaceutical Society: s 57(2C) (as so added). For the meaning of 'Pharmaceutical Society' see PARA 2 note 9 ante.

UPDATE

139 Power to extend or modify exemptions

NOTES--Certain functions under provisions mentioned in this paragraph are 'relevant functions' for the purposes of the Regulatory Enforcement and Sanctions Act 2008 s 4, Sch 3, see LOCAL GOVERNMENT vol 69 (2009) PARA 733.

NOTE 5--SI 1998/1044, SI 2004/2779 revoked: SI 2005/2745.

NOTE 12--Definition of 'registrar' amended: SI 2007/289.

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(ii) Medicinal Products on Prescription Only

140. Necessity for prescription.

Subject to certain exceptions¹, no person² may sell by retail³, or supply in circumstances corresponding to retail sale⁴, a medicinal product⁵ of a description⁶, or falling within a class, specified in an order⁷ made by the appropriate ministers except in accordance with a prescription given by an appropriate practitioner⁸; and no person may administer, otherwise than to himself, any such medicinal product unless he is an appropriate practitioner or a person acting in accordance with the directions of an appropriate practitioner⁹. Any person who contravenes¹⁰ this provision is guilty of an offence¹¹.

The appropriate ministers may by order specify descriptions or classes of medicinal products for these purposes; and, in relation to any description or class so specified, the order must state which of the following, that is to say doctors¹², dentists¹³, veterinary surgeons and veterinary practitioners¹⁴, registered nurses or midwives who are of such a description and comply with such conditions as may be specified in the order¹⁵, and other persons who are of such a description and comply with such conditions as may be specified in the order¹⁶, are to be appropriate practitioners¹⁷. Any order made by the appropriate ministers may provide that the restrictions¹⁸ are to have effect subject to such exemptions as may be specified in the order or, where the appropriate practitioner is a registered nurse or midwife or is some other specified person¹⁹, such modifications as may be so specified²⁰; or that, for the purpose of the restriction on sale or supply²¹, a medicinal product must not be taken to be sold or supplied in accordance with a prescription given by an appropriate practitioner unless such conditions as are prescribed²² by the order are fulfilled²³. Any person who gives a prescription or directions or administers a medicinal product in contravention of a condition imposed²⁴ by an order is guilty of an offence²⁵; and any person who is an appropriate practitioner²⁶ and gives a prescription or directions in respect of a medicinal product of a description or class in relation to which he is not an appropriate practitioner²⁷ is guilty of an offence²⁸.

1 See the Medicines Act 1968 s 58(3)-(5); note 8 infra; and the text to notes 18-23 infra.

2 For the meaning of 'person' see PARA 21 note 7 ante.

3 As to references to retail sale and selling by retail see PARA 7 note 12 ante.

4 As to references to supplying anything in circumstances corresponding to retail sale see PARA 7 note 13 ante.

5 For the meaning of 'medicinal product' see PARA 7 ante.

6 As to the description of medicinal products see PARA 7 note 33 ante.

7 Before making such an order the appropriate ministers must consult the appropriate committee: Medicines Act 1968 s 58(6) (amended by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 8, Sch 1 para 10). For the meaning of 'the appropriate ministers' see PARA 3 ante. For the meaning of 'the appropriate committee' see PARA 15 note 5 ante. The advice of the committee must be taken into account: see the Medicines Act 1968 s 129(7); and PARA 4 ante. As to the exercise of this power to make orders in respect of certain products see PARA 141 post. As to special provisions in relation to new medicinal products see PARA 142 post. As to the making of orders generally see PARA 5 ante.

As to the orders that have been made under the Medicines Act 1968 s 58 (as amended) see the Prescription Only Medicines (Human Use) Order 1997, SI 1997/1830 (amended by SI 1997/2044; SI 1998/108; SI 1998/1178; SI 1998/2081; SI 1999/1044; SI 1999/3463; SI 2000/1917; SI 2000/2899; SI 2000/3231; SI 2001/2777; SI 2001/2889; SI 2001/3942; SI 2002/549; SI 2002/2469; SI 2003/696; SI 2003/1590; SI 2003/2915; SI 2004/2; SI 2004/696; SI 2004/865; SI 2004/1016; SI 2004/1031; SI 2004/1189; SI 2004/1771; SI 2004/2261; SI 2004/2693; SI 2004/3038; SI 2005/765; SI 2005/848; SI 2005/1507; SI 2005/2759); the Medicines (Veterinary Drugs) (Prescription Only) Order 2001, SI 2001/1646; the Medicines (Vaccination against Foot-and-Mouth Disease) Order 2004, SI 2004/2779; and the Medicines for Human Use (Prescribing) Order 2005, SI 2005/765.

8 Medicines Act 1968 s 58(2)(a). This restriction does not apply to the sale or supply of a medicinal product to a patient of his by a doctor or dentist who is an appropriate practitioner (s 58(3)(a)), or to the sale or supply of a medicinal product for administration to an animal or herd under his care by a veterinary surgeon or veterinary practitioner who is an appropriate practitioner (s 58(3)(b)). For the meanings of 'doctor' and 'dentist' see PARA 7 note 10 ante. As to the meaning of 'administer' see PARA 7 note 2 ante. For the meaning of 'animal' see PARA 3 note 7 ante. For the meaning of 'herd' see PARA 50 note 13 ante. For the meanings of 'veterinary surgeon' and 'veterinary practitioner' see PARA 7 note 10 ante. As to appropriate practitioners see the text to notes 12-17 infra.

9 Ibid s 58(2)(b).

10 For the meaning of 'contravene' see PARA 6 note 21 ante.

11 Medicines Act 1968 s 67(2). Such a person is liable on summary conviction to a fine not exceeding the prescribed sum (s 67(4)(a) (amended by virtue of the Magistrates' Courts Act 1980 s 32(2))), or on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both (Medicines Act 1968 s 67(4)(b)). As to the prescribed sum see PARA 32 note 3 ante. As to enforcement, prosecutions, defences and related matters see PARA 176 et seq post. This offence is one of strict liability: *Pharmaceutical Society of Great Britain v Storkwain Ltd* [1986] 2 All ER 635, [1986] 1 WLR 903, HL. As to strict liability see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(1) (2006 Reissue) PARA 15. As to the admissibility of evidence in such cases see *Department for the Environment, Food and Rural Affairs v Atkinson* [2002] EWHC 2029 (Admin), [2002] All ER (D) 116 (Oct), DC. As to sentence see *R v Wileman* [1997] 2 Cr App Rep (S) 326; *R v V* [2002] EWCA Crim 108, [2002] All ER (D) 138, (Jan).

12 Medicines Act 1968 s 58(1)(a).

13 Ibid s 58(1)(b).

14 Ibid s 58(1)(c).

15 Ibid s 58(1)(d) (added by the Medicinal Products Prescription by Nurses etc Act 1992 s 1(1); and substituted by the Nursing and Midwifery Order 2001, SI 2002/253, art 54(3), Sch 5 para 2(a)). As to the registration of nurses and midwives see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 716 et seq.

16 Medicines Act 1968 s 58(1)(e) (added by the Health and Social Care Act 2001 s 63(1), (2)). The descriptions of persons which may be specified in an order by virtue of this provision are the following, or any sub-category of such a description: (1) persons who are registered in the register maintained under the Health Professions Order 2001, SI 2002/254, art 5 (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 325) (Medicines Act 1968 s 58(1A)(a) (s 58(1A) added by the Health and Social Care Act 2001 s 63(1), (2); and the Medicines Act 1968 s 58(1A)(a) substituted by the Health Professions Order 2001 (Consequential Amendments) Order 2003, SI 2003/1590, art 3, Schedule Pt 1 para 6)); (b) persons who are pharmacists (Medicines Act 1968 s 58(1A)(b) (as so added)); (c) persons whose names are entered in a roll or record established by the General Dental Council by virtue of the Dentists Act 1984 s 45 (dental auxiliaries) (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 486) (Medicines Act 1968 s 58(1A)(c) (as so added)); (d) persons who are registered in either of the registers of ophthalmic opticians kept under the Opticians Act 1989 s 7(a) (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 838) (Medicines Act 1968 s 58(1A)(d) (as so added)); (e) persons who are registered osteopaths within the meaning of the Osteopaths Act 1993 (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 503) (Medicines Act 1968 s 58(1A)(e) (as so added)); (f) persons who are registered chiropractors within the meaning of the Chiropractors Act 1994 (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 595) (Medicines Act 1968 s 58(1A)(f) (as so added)); (g) persons who are registered in any register established, continued or maintained under an Order in Council under the Health Act 1999 s 60(1) (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 291) (Medicines Act 1968 s 58(1A)(g) (as so added)); (h) any other description of persons which appears to the appropriate ministers to be a description of persons whose profession is regulated by or under a provision of, or made under, an Act of the Scottish Parliament or Northern Ireland legislation and which the appropriate ministers consider it appropriate to specify (Medicines Act 1968 s 58(1A)(h) (as so added)). For the meaning of 'pharmacist' see PARA 46 note 10 ante. Where an order includes provision by virtue of s 58(1)(e) (as added), the order must specify such conditions as are necessary to secure that any person who is an appropriate practitioner by virtue of the provision may prescribe, give directions or administer only in respect of human use: s 58(1B) (added by the Health and Social Care Act 2001 s 63(1), (2)).

17 Medicines Act 1968 s 58(1).

18 Ie the restrictions under ibid s 58(2)(a) or s 58(2)(b), or both: see the text to notes 1-9 supra.

19 Ie by virtue of provision made under ibid s 58(1)(e) (as added): see the text to note 16 supra.

20 Ibid s 58(4)(a) (amended by the Health and Social Care Act 2001 s 63(1), (4); and the Nursing and Midwifery Order 2001, SI 2002/253, art 54(3), Sch 5 para 2(b)). An order may provide, in relation to a person who is an appropriate practitioner by virtue of being a registered nurse or midwife or some other specified person, that such a person may:

68 (1) give a prescription for a medicinal product falling within a description or class specified in the order (Medicines Act 1968 s 58(4A)(a) (s 58(4A)-(4C) added by the Health and Social Care Act 2001 s 63(1), (5));

69 (2) administer any such medicinal product (Medicines Act 1968 s 58(4A)(b) (as so added)); or

70 (3) give directions for the administration of any such medicinal product (s 58(4A)(c) (as so added)),

only where he complies with such conditions as may be specified in the order in respect of the cases or circumstances in which he may do so (s 58(4A) (as so added)). An order may provide, in relation to any such condition, for the condition to have effect subject to such exemptions as may be specified in the order: s 58(4B) (as so added). Where a condition is specified by virtue of s 58(4A) (as added), any prescription or direction given by a person in contravention of the condition is not (subject to such exemptions or modifications as may be specified in the order by virtue of s 58(4)(a)) given by an appropriate practitioner for the purposes of s 58(2) (a), (b) (see the text to notes 1-9 supra): s 58(4C) (as so added). Any exemption conferred or modification made by an order in accordance with s 58(4)(a) or 58(4B) (as added) may be conferred or made subject to such conditions or limitations as may be specified in the order: s 58(5) (amended by the Medicinal Products: Prescription by Nurses etc Act 1992 s 1; and the Health and Social Care Act 2001 s 63(1), (6)).

21 Ie under the Medicines Act 1968 s 58(2)(a): see the text to notes 1-8 supra.

22 For the meaning of 'prescribed' see PARA 56 note 3 ante.

23 Medicines Act 1968 s 58(4)(b).

24 Ie under ibid s 58(4A) (as added): see note 20 supra.

25 Ibid s 67(1A) (s 67(1A), (1B) added by the Health and Social Care Act 2001 s 63(1), (7)(a)). For the penalty for such an offence see the Medicines Act 1968 s 67(4); and note 11 supra.

26 Ibid s 67(1B)(a) (as added: see note 25 supra).

27 Ibid s 67(1B)(b) (as added: see note 25 supra).

28 Ibid s 67(1B) (as added: see note 25 supra). For the penalty for such an offence see the Medicines Act 1968 s 67(4); and note 11 supra.

UPDATE

140 Necessity for prescription

TEXT AND NOTES 1-8--A person who has in his possession a medicinal product to which the 1968 Act s 58(2)(a) applies, with the intention of supplying it otherwise than in accordance with the requirements of that provision, is guilty of an offence: s 67(3A) (added by the Medicines for Human Use (Manufacturing, Wholesale Dealing and Miscellaneous Amendments) Regulations 2005, SI 2005/2789). Any person guilty of such an offence is liable, on summary conviction, to a fine not exceeding the prescribed sum, and, on conviction on indictment, to a fine or to imprisonment for a term not exceeding two years or to both: 1968 Act s 67(4)(b) (amended by SI 2005/2789). As to the prescribed sum see PARA 32 NOTE 3. As to enforcement, prosecutions, defences and related matters see PARA 176 et seq.

NOTE 7--SI 2001/1646, SI 2004/2779 revoked: SI 2005/2745. SI 1997/1830 further amended: see PARA 48. See also the Medicines for Human Use (Prescribing by EEA Practitioners) Regulations 2008, SI 2008/1692 (amended by SI 2008/3097).

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141. Requirement to specify certain products as prescription only products.

In relation to medicinal products¹ for human use, the appropriate ministers² must so exercise their powers to make orders in respect of prescription only medicinal products³ as to secure that every product in respect of which a product licence is granted⁴, to which the Directive on the Community code relating to medicinal products for human use⁵ applies⁶, and to which specified conditions apply⁷, falls within one of the descriptions or classes specified in such an order⁸. The specified conditions are that the product is one which: (1) is likely to present a direct or indirect danger to human health, even when used correctly, if used without the supervision of a doctor or dentist⁹; or (2) is frequently and to a very wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health¹⁰; or (3) contains substances or preparations of substances of which the activity requires, or the side-effects require, further investigation¹¹; or (4) is normally prescribed by a doctor or dentist for parental administration¹².

Similarly, in relation to medicinal products for veterinary use, the appropriate ministers must so exercise their powers to make orders¹³ as to secure that every product in respect of which a product licence is granted¹⁴, to which the Directive on the approximation of the laws of the member states relating to veterinary medicinal products¹⁵ applies¹⁶, and to which specified conditions apply¹⁷, falls within one of the descriptions or classes specified in such an order¹⁸. The specified conditions are that the product is one which: (a) is subject to restrictions on supply or use resulting from the Narcotic Drugs Convention, the Psychotropic Substances Convention or any Community obligation¹⁹, other than an obligation under the Directive²⁰; or (b) is likely to cause unnecessary risk to the target species, humans or the environment unless special precautions are taken by a veterinary surgeon or veterinary practitioner²¹; or (c) is intended for a treatment or condition which requires a precise prior diagnosis²²; or (d) may cause effects which impede or interfere with subsequent diagnosis or treatment²³; or (e) is a new product containing an active ingredient where a product licence for veterinary use was granted in respect of the ingredient less than five years prior to the relevant date²⁴ in relation to the product unless, having regard to the information and particulars provided by the applicant for the licence²⁵ or experience acquired in the use of the product²⁶, the appropriate ministers are satisfied that the conditions in heads (a) to (d) above do not apply to the product²⁷.

1 For the meaning of 'medicinal product' see PARA 7 ante.

2 For the meaning of 'the appropriate ministers' see PARA 3 ante.

3 Ie under the Medicines Act 1968 s 58 (as amended): see PARA 140 ante.

4 Ibid s 58A(1)(a) (s 58A added by the Medicines Act 1968 (Amendment) (No 2) Regulations 1992, SI 1992/3271, reg 2). For the meaning of 'product licence' see PARA 44 note 5 ante.

5 Ie European Parliament and Council Directive EC 2001/83 (OJ L311, 28.11.2001, p 67) on the Community code relating to medicinal products for human use (as amended)

6 Medicines Act 1968 s 58A(1)(b) (as added: see note 4 supra).

7 Ibid s 58A(1)(c) (as added: see note 4 supra).

8 Ibid s 58A(1) (as added: see note 4 supra). Section 58A(1) (as added) does not apply in relation to any product if the appropriate ministers so determine having regard to: (1) the maximum single dose (s 58A(4)(a) (as so added)); (2) the maximum daily dose (s 58A(4)(b) (as so added)); (3) the strength of the product (s 58A(4)(c) (as so added)); (4) its pharmaceutical form (s 58A(4)(d) (as so added)); (5) its packaging (s 58A(4)(e) (as so added)); or (6) such other circumstances relating to its use as may be specified in the determination (s 58A(4)(f) (as so added)). For the meaning of 'package' see PARA 152 note 4 post.

9 Ibid s 58A(2)(a) (as added: see note 4 supra). For the meanings of 'doctor' and 'dentist' see PARA 7 note 10 ante. In considering whether conditions under s 58A(2) (as added) apply to a product, the appropriate ministers must take into account whether the product: (1) contains a substance which is listed in any of Schedules I, II or IV to the Narcotic Drugs Convention (where the product is not a preparation listed in Schedule III to that Convention) (Medicines Act 1968 s 58A(3)(a) (as so added)); or (2) contains a substance which is listed in any of Schedules I to IV of the Psychotropic Substances Convention (where the product is not a preparation which may be exempted from measures of control in accordance with article 3(2), (3)) (Medicines Act 1968 s 58A(3)(b) (as so added)); or (3) is likely, if incorrectly used, to present a substantial risk of medicinal abuse, or to lead to addiction, or to be used for illegal purposes (s 58A(3)(c) (as so added)); or (4) contains a substance which, by reason of its novelty or properties, might fall within head (3) supra, but as to which there is insufficient information available to determine whether it does so fall (s 58A(3)(d) (as so added)); or (5) by reason of its pharmaceutical characteristics or novelty, or in the interests of public health, is reserved for treatments which can only be followed in a hospital (s 58A(3)(e) (as so added)); or (6) is used in the treatment of conditions which must be diagnosed in a hospital or in an institution with special diagnostic facilities (although administration and subsequent supervision may be carried out elsewhere) (s 58A(3)(f) (as so added)); or (7) is intended for outpatients but may produce very serious side-effects which would require a prescription drawn up as required by a specialist and special supervision throughout the treatment (s 58A(3)(g) (as so added)). For these purposes, 'the Narcotic Drugs Convention' means the Single Convention on Narcotic Drugs signed by the United Kingdom on 30 March 1961 (New York 30 March to 1 August 1961; TS 34 (1965); Cmnd 2631) as amended by the Protocol Amending the Single Convention on Narcotic Drugs signed by the United Kingdom on 25 March 1972 (Geneva, 25 March to 31 December 1972; TS 23 (1979); Cmd 7466); and 'the Psychotropic Substances Convention' means the Convention on Psychotropic Substances (Vienna, 21 February 1971; TS 51 (1993); Cmnd 2307); Medicines Act 1968 s 58A(5) (as so added); 58B(5) (as added: see note 14 infra). For the meaning of 'substance' see PARA 7 note 1 ante. For the meaning of 'hospital' see PARA 86 note 2 ante. As to the meaning of 'administer' see PARA 7 note 2 ante. For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

10 Ibid s 58A(2)(b) (as added (see note 4 supra); and amended by the Medicines (Codification Amendments Etc) Regulations 2002, SI 2002/236, reg 2(a)(v)). See also note 9 supra.

11 Medicines Act 1968 s 58A(2)(c) (as added: see note 4 supra). See also note 9 supra.

12 Ibid s 58A(2)(d) (as added: see note 4 supra). See also note 9 supra.

13 Ie under ibid s 58(1): see PARA 140 ante.

14 Ibid s 58B(1)(a) (s 58B added by the Medicines Act 1968 (Amendment) (No 2) Regulations 1992, SI 1992/3271, reg 2).

15 Ie EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) on the approximation of the laws of the member states relating to veterinary medicinal products (as amended).

16 Medicines Act 1968 s 58B(1)(b) (as added: see note 14 supra).

17 Ibid s 58B(1)(c) (as added: see note 14 supra).

18 Ibid s 58B(1) (as added: see note 14 supra).

19 For the meaning of 'Community obligation' see the European Communities Act 1972 s 1, Sch 1 Pt II; and the Interpretation Act 1978 s 5, Sch 1.

20 Medicines Act 1968 s 58B(2)(a) (as added: see note 14 supra).

21 Ibid s 58B(2)(b) (as added: see note 14 supra). For the meanings of 'veterinary surgeon' and 'veterinary practitioner' see PARA 7 note 10 ante.

22 Ibid s 58B(2)(c) (as added: see note 14 supra).

23 Ibid s 58B(2)(d) (as added: see note 14 supra).

24 The relevant date in relation to a product is the date on which it falls to be determined by the appropriate ministers whether ibid s 58B(3) (as added) applies to the product: s 58B(4) (as added: see note 14 supra).

- 25 Ibid s 58B(3)(a) (as added: see note 14 supra). As to applications for product licences see PARA 56 ante.
- 26 Ibid s 58B(3)(b) (as added: see note 14 supra).
- 27 Ibid s 58B(3) (as added: see note 14 supra).

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142. Special provisions in relation to new medicinal products.

Where an order specifying descriptions or classes of medicinal products¹ as prescription only medicines² is made so as to apply to all medicinal products of a specified class which are of a description³ in respect of which certain conditions are fulfilled which make them new medicinal products⁴, the restrictions as to sale or supply or administration⁵ do not apply by virtue of the order to medicinal products of any description except during a period which begins with the relevant date⁶ in relation to medicinal products of that description and which is of such duration as may be specified in the order⁷. Where such an order is made, it may provide that the restrictions are to have effect subject to any exemptions specified in a direction given by the appropriate ministers⁸ relating to medicinal products of a particular description specified in that direction⁹.

1 For the meaning of 'medicinal product' see PARA 7 ante.

2 I.e. an order under the Medicines Act 1968 s 58 (as amended): see PARA 140 ante.

3 As to the description of medicinal products see PARA 7 note 33 ante.

4 Medicines Act 1968 s 59(1). The conditions are: (1) that medicinal products of that description were not effectively on the market in the United Kingdom immediately before 1 September 1971 (s 59(1)(a)); (2) that a product licence applies to medicinal products of that description, whether it also applies to medicinal products of other descriptions or not (s 59(1)(b)); and (3) that before the grant of that licence no product licence had been granted which was applicable to medicinal products of that description (s 59(1)(c)). As to the meaning of 'effectively on the market in the United Kingdom' see PARA 44 note 18 ante. For the meaning of 'United Kingdom' see PARA 7 note 3 ante. For the meaning of 'product licence' see PARA 44 note 5 ante.

5 I.e. the restrictions imposed by *ibid* s 58(2): see PARA 140 ante.

6 The 'relevant date' means the date on which the order comes into force or the date on which the product licence applicable to medicinal products of that description (as mentioned in *ibid* s 59(1)(b): see note 4 *supra*) comes into operation, whichever is the later: s 59(3).

7 *Ibid* s 59(2)(a).

8 For the meaning of 'the appropriate ministers' see PARA 3 ante.

9 See the Medicines Act 1968 s 59(2)(b).

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(iii) Restrictions by Regulations on certain Medicinal Products

143. Restricted sale, supply and administration.

Regulations made by the appropriate ministers¹ may provide that no person² may sell by retail³, or supply in circumstances corresponding to retail sale⁴, a medicinal product of a description⁵ specified in the regulations, or falling within a class so specified, unless:

- 132 (1) he is a practitioner⁶ holding a certificate issued for these purposes by the appropriate ministers in respect of medicinal products of that description or falling within that class, or a person acting in accordance with the directions of such a practitioner, and the product is so sold or supplied for the purpose of being administered⁷ in accordance with the directions of that practitioner⁸; or
- 133 (2) he is a person lawfully conducting a retail pharmacy business⁹ and the product is so sold or supplied in accordance with a prescription given by such a practitioner¹⁰.

Any such regulations may provide that no person may administer, otherwise than to himself, a medicinal product of a description specified in the regulations, or falling within a class so specified, unless he is such a practitioner as is mentioned in head (1) above or a person acting in accordance with the directions of such a practitioner¹¹. However, the powers conferred by these provisions¹² are not exercisable in respect of medicinal products of a particular description, or falling within a particular class, except where it appears to the appropriate ministers that the sale by retail, or supply in circumstances corresponding to retail sale, or the administration, of such products requires specialised knowledge on the part of the practitioner by whom or under whose directions they are sold, supplied or administered¹³.

Any regulations made in respect of a particular description or class of medicinal products may specify the qualifications and experience which an applicant for a certificate in respect of that description or class of medicinal products must have, and may provide for the appointment of a committee to advise the appropriate ministers, in such cases as may be prescribed by or determined in accordance with the regulations, with respect to the grant, renewal, suspension and revocation of such certificates¹⁴. Any such regulations must include provision as to the grant, duration, renewal, suspension and revocation of certificates, including provision for affording to an applicant for the grant or renewal of such a certificate, where the appropriate ministers propose to refuse to grant or renew it¹⁵, and to the holder¹⁶ of such a certificate, where the appropriate ministers propose to suspend or revoke it¹⁷, an opportunity of appearing before, and being heard by, a person appointed for the purpose by the appropriate ministers or of making representations in writing to those ministers with respect to that proposal¹⁸.

Any person who contravenes¹⁹ any regulations made under these provisions is guilty of an offence²⁰.

¹ Before making any such regulations the appropriate ministers must consult the appropriate committee: Medicines Act 1968 s 60(7) (amended by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 8, Sch 1 para 11). The advice of the committee must be taken into account: see the Medicines Act 1968 s

129(7); and PARA 4 ante. For the meaning of 'the appropriate ministers' see PARA 3 ante. For the meaning of 'the appropriate committee' see PARA 15 note 5 ante. As to the making of regulations see PARA 5 ante.

2 For the meaning of 'person' see PARA 21 note 7 ante.

3 As to references to retail sale and selling by retail see PARA 7 note 12 ante.

4 As to references to supplying anything in circumstances corresponding to retail sale see PARA 7 note 13 ante.

5 For the meaning of 'medicinal product' see PARA 7 ante. As to the description of medicinal products see PARA 7 note 33 ante.

6 For the meaning of 'practitioner' see PARA 7 note 10 ante.

7 As to the meaning of 'administer' see PARA 7 note 2 ante.

8 Medicines Act 1968 s 60(1)(a).

9 For the meaning of 'retail pharmacy business' see PARA 51 note 3 ante. As to the lawful conduct of such a business see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 909 et seq.

10 Medicines Act 1968 s 60(1)(b). The regulations may provide that a medicinal product must not be taken to be sold or supplied in accordance with a prescription unless such conditions as are prescribed by the regulations are fulfilled: s 60(6). For the meaning of 'prescribed' see PARA 56 note 3 ante. As to the regulations that have been made see the Medicines (Administration of Radioactive Substances) Regulations 1978, SI 1978/1006 (amended by SI 1995/2147; SI 2005/2754).

11 Medicines Act 1968 s 60(2).

12 le by ibid s 60(1), (2): see the text and notes 1-11 supra.

13 Ibid s 60(3).

14 Ibid s 60(4). The ministers must provide any such committee with such staff and such accommodation, services and other facilities as appear to the ministers to be necessary or expedient for the proper performance of its functions: s 5(1), Sch 1A para 7 (s 5(1) amended, and Sch 1A added, by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, regs 6(1), 7). For the meaning of 'the ministers' see PARA 3 note 3 ante. The validity of any proceedings of such a committee is not affected by a vacancy among the members of that committee, or a defect in the appointment of any member of that committee: Medicines Act 1968 Sch 1A para 8 (as so added). Such a committee has the power to regulate its procedure: Sch 1A para 9(3) (as so added). The ministers may pay to the members of such a committee such remuneration (if any) and such allowances as may be determined by the ministers with the consent of the Treasury (Sch 1A para 10 (as so added)), and the ministers must defray any expenses incurred with their approval by such a committee (Sch 1A para 11 (as so added)). As to the Treasury see CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARAS 512-517. As to the defraying of expenses under the Medicines Act 1968 see PARA 11 ante. No such committee is to be taken to be the servant or agent of the Crown or to enjoy any status or immunity of the Crown: Sch 1A para 12 (as so added). As to the legal status of such bodies see CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARA 951 et seq.

15 Ibid s 60(5)(a).

16 As to references to the holder of a certificate see PARA 66 note 5 ante.

17 Medicines Act 1968 s 60(5)(b).

18 Ibid s 60(5). As to the procedure to be followed by a person appointed by the appropriate ministers see the Medicines Act 1968 (Hearings by Persons Appointed) Rules 1986, SI 1986/1761.

19 For the meaning of 'contravene' see PARA 6 note 21 ante.

20 Medicines Act 1968 s 67(2). Such a person is liable on summary conviction to a fine not exceeding the prescribed sum (s 67(4)(a) (amended by virtue of the Magistrates' Courts Act 1980 s 32(2))), or on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both (Medicines Act 1968 s 67(4)(b)). As to the prescribed sum see PARA 32 note 3 ante. As to enforcement, prosecutions, defences and related matters see PARA 176 et seq post.

UPDATE

143 Restricted sale, supply and administration

NOTE 10--SI 1978/1006 further amended: SI 2006/2806.

NOTE 18--SI 1986/1761 amended: SI 2005/2745, SI 2008/2683.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(7) SALE AND SUPPLY OF MEDICINAL PRODUCTS/(iii) Restrictions by Regulations on certain Medicinal Products/144. Special restrictions on persons to be supplied.

144. Special restrictions on persons to be supplied.

The appropriate ministers¹ may by regulations² provide, either in respect of medicinal products³ generally or in respect of medicinal products of a description⁴ or falling within a class specified in the regulations, that, subject to such exceptions as may be so specified, no person⁵ being the holder of a product licence⁶, or in the course of business⁷ carried on by him and consisting wholly or partly of manufacturing⁸ medicinal products or of selling medicinal products by way of wholesale dealing⁹, is to sell or supply any medicinal product to which the regulations apply to any person who does not fall within a class specified in the regulations¹⁰.

Any person who contravenes¹¹ any such regulations is guilty of an offence¹².

1 For the meaning of 'the appropriate ministers' see PARA 3 ante.

2 As to the making of regulations see PARA 5 ante.

3 For the meaning of 'medicinal product' see PARA 7 ante.

4 As to the description of medicinal products see PARA 7 note 33 ante.

5 For the meaning of 'person' see PARA 21 note 7 ante.

6 Medicines Act 1968 s 61(a). For the meaning of 'product licence' see PARA 44 note 5 ante. As to references to the holder of a licence see PARA 66 note 5 ante.

7 As to the meaning of 'business' see PARA 7 note 11 ante.

8 As to the meaning of 'manufacture' see PARA 7 note 2 ante.

9 Medicines Act 1968 s 61(b). As to the meaning of 'wholesale dealing' see PARA 47 note 5 ante.

10 Ibid s 61. As to the regulations that have been made under s 61 see the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980, SI 1980/1923 (amended by SI 1982/28; SI 1990/1124; SI 1990/2487; SI 1992/2938; SI 1994/2411; SI 1994/3142; SI 1994/3144; SI 1995/3215; SI 1997/1831; SI 1997/2045; SI 1998/1045; SI 1999/644; SI 1999/2510; SI 2000/7; SI 2000/1070; SI 2000/1918; SI 2000/2494; SI 2001/3849; SI 2002/2469; SI 2003/698; SI 2004/696; SI 2004/1771; SI 2005/764; SI 2005/1520; SI 2005/2750); and the Medicines (Advertising) Regulations 1994, SI 1994/1932 (amended by SI 1994/3144; SI 1996/1552; SI 1999/267; SI 2002/236; SI 2003/2321; SI 2004/1480; SI 2005/2787). The Medicines Act 1968 s 61 has effect in relation to a traditional herbal registration (see PARA 230 post): Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, SI 2005/2750, reg 10(4).

11 For the meaning of 'contravene' see PARA 6 note 21 ante.

12 Medicines Act 1968 s 67(2). Such a person is liable on summary conviction to a fine not exceeding the prescribed sum (s 67(4)(a) (amended by virtue of the Magistrates' Courts Act 1980 s 32(2))), or on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both (Medicines Act 1968 s 67(4)(b)). As to the prescribed sum see PARA 32 note 3 ante. As to enforcement, prosecutions, defences and related matters see PARA 176 et seq post.

UPDATE

144 Special restrictions on persons to be supplied

NOTE 10--SI 1980/1923 further amended: see PARA 6 NOTE 2.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(7) SALE AND SUPPLY OF MEDICINAL PRODUCTS/(iv) Record Keeping for Veterinary Medicinal Products/145. Record keeping.

(iv) Record Keeping for Veterinary Medicinal Products

145. Record keeping.

Any person¹ who sells veterinary medicinal products² by retail³ must comply with the following requirements in relation to those products⁴. For each incoming and outgoing transaction a record must be kept of the date of the transaction⁵, the identity of the product⁶, the manufacturer's batch number⁷, the quantity received or supplied⁸, the name and address of the supplier or recipient⁹, and, where relevant, the name and address of the prescribing veterinarian and a copy of the prescription¹⁰. At least once a year a detailed audit of all such transactions must be carried out and recorded, with incoming and outgoing products reconciled with those held in stock, and any discrepancies recorded¹¹. All such records must be durable, but may be kept by electronic means, and must be kept for a period of three years from the date of the transaction or audit, and made available on request to a person duly authorised in writing by any person or body having a duty¹² of enforcement¹³.

It is the duty of the Secretary of State in relation to England¹⁴ and the National Assembly for Wales in relation to Wales¹⁵ to enforce these provisions¹⁶, concurrently with the Royal Pharmaceutical Society of Great Britain¹⁷. Any person who contravenes the requirements relating to record keeping¹⁸ is guilty of an offence¹⁹. Where an offence which has been committed by a body corporate is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, any director, manager, secretary or other similar officer of the body corporate or any person who was purporting to act in any such capacity he, as well as the body corporate, is guilty of that offence and liable to be proceeded against and punished accordingly²⁰.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 'Veterinary medicinal product' has the meaning given in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) on the approximation of the laws of the member states relating to veterinary medicinal products, art 1.2: Retailers' Records for Veterinary Medicinal Products Regulations 2000, SI 2000/7, reg 2. For the meaning of 'member state' see the European Communities Act 1972 s 1(2), Sch 1 Pt II; and the Interpretation Act 1978 s 5, Sch 1.

3 The Retailers' Records for Veterinary Medicinal Products Regulations 2000, SI 2000/7, reg 3 only applies to the sale by retail of: (1) veterinary medicinal products intended for administration to animals whose flesh or products are intended for human consumption and in respect of which a withdrawal period must be observed (reg 4(1)(a)); and (2) other veterinary medicinal products intended for administration to such animals unless the products are on a general sale list within the meaning of the Medicines Act 1968 s 51(2) (see PARA 133 ante) (Retailers' Records for Veterinary Medicinal Products Regulations 2000, SI 2000/7, regs 2, 4(1)(b)). Regulation 3 does not apply to the sale by retail of a veterinary medicinal product by a person required to keep a record of the sale by virtue of an order made the Medicines Act 1968 s 57 (as amended) (see PARA 139 ante) relating to veterinary drugs which is for the time being in force: Retailers' Records for Veterinary Medicinal Products Regulations 2000, SI 2000/7, regs 2, 4(2). For the meaning of 'veterinary drug' see PARA 3 note 7 ante; definition applied by reg 4(2).

4 Ibid reg 3(1).

5 Ibid reg 3(2)(a).

6 Ibid reg 3(2)(b).

7 Ibid reg 3(2)(c).

8 Ibid reg 3(2)(d).

9 Ibid reg 3(2)(e).

10 Ibid reg 3(2)(f).

11 Ibid reg 3(3).

12 Ie given by ibid reg 5: see the text to notes 14-17 infra.

13 Ibid reg 3(4).

14 Ibid reg 5(1)(a); Ministry of Agriculture, Fisheries and Food (Dissolution) Order 2002, SI 2002/794, art 2(2). As to the Secretary of State see PARA 3 note 3 ante. For the meaning of 'England' see PARA 7 note 3 ante.

15 Retailers' Records for Veterinary Medicinal Products Regulations 2000, SI 2000/7, reg 5(1)(c). As to the National Assembly for Wales see CONSTITUTIONAL LAW AND HUMAN RIGHTS. For the meaning of 'Wales' see PARA 7 note 3 ante.

16 Ibid reg 5(1). Any duty of enforcement imposed by reg 5(1), (2) (see the text and note 17 infra) is deemed to be a duty imposed by the Medicines Act 1968 s 108 (see PARA 168 post); and the provisions of ss 111-114 (other than ss 111(3), 112(7)) (see PARAS 169-172 post), s 119 (see PARA 175 post) and Sch 3 (see PARA 171 post) apply for the purposes of the Retailers' Records for Veterinary Medicinal Products Regulations 2000, SI 2000/7, as if they had been made under the Act, and as if an offence contrary to, and proceedings under, the regulations were an offence and proceedings under the Act: Retailers' Records for Veterinary Medicinal Products Regulations 2000, SI 2000/7, reg 5(3).

17 See ibid reg 5(2). This duty cannot be exercised in relation to the types of location specified in the Medicines Act 1968 s 108(9) (see PARA 168 post): Retailers' Records for Veterinary Medicinal Products Regulations 2000, SI 2000/7, reg 5(2). See also note 16 supra. As to the Royal Pharmaceutical Society of Great Britain see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 881 et seq.

18 Ie under ibid reg 3: see the text to notes 1-13 supra.

19 See ibid reg 6(1). Such a person is liable on summary conviction to a fine not exceeding the statutory maximum (reg 6(1)(a)), or on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both (reg 6(1)(b)). As to the statutory maximum see PARA 32 note 3 ante.

20 Ibid reg 6(2). When the affairs of a body corporate are managed by its members this provision applies in relation to the acts and defaults of a member in connection with his functions of management as if he were a director of the body corporate: reg 6(3). As to bodies corporate see COMPANIES; CORPORATIONS.

UPDATE

145 Record keeping

TEXT AND NOTES--SI 2000/7 now replaced by Veterinary Medicines Regulations 2009, SI 2009/2297: see PARAS 34A-34D.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(8) QUALITY AND STANDARDS; COMPENDIA/(i) Quality and Compliance with Standards/146. Adulteration of medicinal products.

(8) QUALITY AND STANDARDS; COMPENDIA

(i) Quality and Compliance with Standards

146. Adulteration of medicinal products.

No person¹ may add any substance² to, or abstract³ any substance from, a medicinal product⁴ so as to affect injuriously⁵ the composition⁶ of the product, with intent that the product is to be sold or supplied in that state⁷, or sell or supply, or offer or expose for sale or supply, or have in his possession for the purpose of sale or supply, any medicinal product whose composition has been injuriously affected by the addition or abstraction of any substance⁸.

Any person who contravenes⁹ this provision is guilty of an offence¹⁰.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 For the meaning of 'substance' see PARA 7 note 1 ante.

3 As to the meaning of 'abstract' see *Penrice v Brander* 1921 JC 63; *Bridges v Griffin* [1925] 2 KB 233; *Dearden v Whiteley* (1916) 85 LJB 1420, DC.

4 For the meaning of 'medicinal product' see PARA 7 ante.

5 This phrase is not defined for the purposes of the Medicines Act 1968. It would seem that, since it is the composition of the product which is, or is not, injuriously affected, the likelihood of actual injury to the eventual consumer is irrelevant. However, it is not clear how the ingredients, proportions, degrees of strength, quality and purity of a medicinal product can themselves be injured. The efficacy of the product is not mentioned in the definition of 'composition' (see note 6 infra). In relation to the phrase 'injuriously affected by the execution of the works' in the Lands Clauses Consolidation Act 1845, Bramwell B explained the meaning as follows: 'The word 'injuriously' does not mean 'wrongfully' affected . . . It means hurtfully or 'damnously' affected. As when we say of a man that he fell and injured his leg. We do not mean that his leg was wronged, but that it was hurt. We mean he fell, and his leg was injuriously, that is to say, hurtfully affected': *McCarthy v Metropolitan Board of Works* (1872) LR 8 CP 191 at 208-209, Ex Ch. Cf, however, *Roberts v Gwyrfa District Council* [1899] 1 Ch 583, where Kekewich J held that the Lands Clauses Consolidation Act 1845 decisions on the meaning of the phrase were irrelevant in a great measure to the construction of a similar phrase in the Public Health Act 1875 s 332 (repealed), referring to injuriously affecting any reservoir, canal, river or stream; affd [1899] 2 Ch 608, CA. The Food and Drugs Act 1955 s 1(2) (repealed), which contained provision similar to that in the Medicines Act 1968 s 63, referred to affecting injuriously the quality, constitution or potency of the drug. See also *Re Clarendon Development Ltd* (1965) 50 DLR (2d) 521, Nova Scotia SC (a Canadian planning decision).

6 For the meaning of 'composition' see PARA 44 note 14 ante.

7 Medicines Act 1968 s 63(a).

8 Ibid s 63(b). A person charged with contravening s 63(b) may in certain circumstances raise the defence that he purchased the article to which the charge relates under a warranty as to its quality: see s 122; and PARA 180 post. Certain presumptions apply to such an offence: see PARA 184 post.

9 For the meaning of 'contravene' see PARA 6 note 21 ante.

10 Medicines Act 1968 s 67(2). Such a person is liable on summary conviction to a fine not exceeding the prescribed sum (s 67(4)(a) (amended by virtue of the Magistrates' Courts Act 1980 s 32(2)), or on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both (Medicines Act 1968 s 67(4)(b)). As to the prescribed sum see PARA 32 note 3 ante. As to enforcement, prosecution, defences and related matters see PARA 176 et seq post.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(8) QUALITY AND STANDARDS; COMPENDIA/(i) Quality and Compliance with Standards/147. Protection of purchasers of medicinal products.

147. Protection of purchasers of medicinal products.

No person¹ may, to the prejudice of the purchaser², sell any medicinal product³ which is not of the nature or quality demanded⁴ by the purchaser⁵. Where a medicinal product is sold or supplied in pursuance of a prescription given by a practitioner⁶, no person may sell or supply, to the prejudice of the purchaser or the person for whom the product was prescribed by the practitioner, any medicinal product which is not of the nature or quality specified in the prescription⁷.

These provisions must not be taken to be contravened⁸ by reason only that: (1) a medicinal product contains some extraneous matter, if it is proved that the presence of the matter was an inevitable consequence of the process of manufacture⁹ of the product¹⁰; or (2) a substance¹¹ has been added to, or abstracted¹² from, the medicinal product, if it is proved that: (a) the addition or abstraction was not carried out fraudulently, and did not injuriously affect¹³ the composition¹⁴ of the product¹⁵; and (b) the product was sold having attached to it, or to a container¹⁶ or package¹⁷ in which it was sold, a conspicuous notice of adequate size and legibly printed specifying the substance added or abstracted¹⁸.

Any person who contravenes these provisions is guilty of an offence¹⁹.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 For the purposes of the Medicines Act 1968 s 64, the sale of a medicinal product is not to be taken to be otherwise than to the prejudice of the purchaser by reason only that he buys it for the purpose of analysis or examination: s 64(2). For the meaning of 'to the prejudice of the purchaser' see the Food Safety Act 1990 s 14; and FOOD vol 18(2) (Reissue) PARAS 360-362. It seems that 'prejudice' is wider than 'injury' or 'damage', and that it is not necessary to prove actual harm done to the purchaser: see *Hoyle v Hitchman* (1879) 4 QBD 233, DC.

3 For the meaning of 'medicinal product' see PARA 7 ante.

4 For the meaning given to this expression under the food and drugs legislation (from which it is derived) see the Food Safety Act 1990 s 14; and FOOD vol 18(2) (Reissue) PARAS 360-362.

5 Medicines Act 1968 s 64(1). By analogy with cases under the similar provisions in the food and drugs legislation, it would seem that, whereas a deficiency either in nature or in quality is sufficient, an information alleging the sale of an article 'which was not of the nature or not of the quality' demanded would be bad for duplicity: see *Bastin v Davies* [1950] 2 KB 579, [1950] 1 All ER 1095, DC; and cf *Moore v Ray* [1951] 1 KB 98, [1950] 2 All ER 561, DC. See FOOD vol 18(2) (Reissue) PARA 360. A person charged with contravening the Medicines Act 1968 s 64 may in certain circumstances raise the defence that he purchased the article to which the charge relates under a warranty as to its quality: see s 122; and PARA 180 post.

6 For the meaning of 'practitioner' see PARA 7 note 10 ante.

7 Medicines Act 1968 s 64(1), (5). The provisions of s 64(1)-(4) apply to samples taken by a sampling officer in the exercise of his powers under s 112 (see PARA 170 post) as if the taking of the sample were a sale to him: s 112(9), Sch 3 para 29.

8 For the meaning of 'contravene' see PARA 6 note 21 ante.

9 As to the meaning of 'manufacture' see PARA 7 note 2 ante.

10 Medicines Act 1968 s 64(3). See also note 7 supra.

11 For the meaning of 'substance' see PARA 7 note 1 ante.

12 As to the meaning of 'abstract' see PARA 146 note 3 ante.

13 See PARA 146 note 5 ante.

14 For the meaning of 'composition' see PARA 44 note 14 ante.

15 Medicines Act 1968 s 64(4)(a).

16 For the meaning of 'container' see PARA 152 note 4 post.

17 For the meaning of 'package' see PARA 152 note 4 post.

18 Medicines Act 1968 s 64(4)(b). See also note 7 supra. Cf the Food Safety Act 1990 s 14; and FOOD vol 18(2) (Reissue) PARA 360.

19 Medicines Act 1968 s 67(2). Such a person is liable on summary conviction to a fine not exceeding the prescribed sum (s 67(4)(a) (amended by virtue of the Magistrates' Courts Act 1980 s 32(2)), or on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both (Medicines Act 1968 s 67(4)(b)). As to the prescribed sum see PARA 32 note 3 ante. As to enforcement, prosecution, defences and related matters see PARA 176 et seq post.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(8) QUALITY AND STANDARDS; COMPENDIA/(i) Quality and Compliance with Standards/148. Compliance with standards specified in published monographs.

148. Compliance with standards specified in published monographs.

No person¹, in the course of a business² carried on by him, may: (1) sell a medicinal product³ which has been demanded by the purchaser by, or by express reference to, a particular name⁴, or sell or supply a medicinal product in pursuance of a prescription given by a practitioner⁵ in which the product required is described by, or by express reference to, a particular name⁶, if, in either case, that name is a name at the head of the relevant monograph⁷ and the product does not comply with the standard specified in that monograph⁸; (2) sell or supply a medicinal product which, in the course of that business, has been offered or exposed for sale and has been so offered or exposed for sale by, or by express reference to, a particular name, if that name is a name at the head of the relevant monograph and the product does not comply with the standard specified in that monograph⁹. Where a medicinal product is sold or supplied in any such circumstances¹⁰ and the name in question is the name, not of the product itself, but of an active ingredient¹¹ of the product, the product must be taken not to comply with the standard specified in the relevant monograph if, in so far as it consists of that ingredient, it does not comply with the standard so specified¹². Any person who contravenes any of these provisions is guilty of an offence¹³.

'The relevant monograph'¹⁴: (a) if, together with the name, there is specified a particular edition¹⁵ of a particular publication¹⁶, means the monograph, if any, headed by that name in that edition of that publication, or, if there is no such monograph in that edition, means the appropriate current¹⁷ monograph¹⁸, if any, headed by that name¹⁹; or (b) if, together with that name, there is specified a particular publication, but not a particular edition, means the monograph, if any, headed by that name in the current edition of that publication, or, if there is no such monograph in that edition, means the appropriate current monograph, if any, headed by that name, or, in default of such a monograph, means the monograph headed by that name in the latest edition of the specified publication which contained a monograph so headed²⁰; or (c) if no publication is specified together with that name, means the appropriate current monograph, if any²¹.

The health ministers²², by notice published in the Gazette²³, may declare that the European Pharmacopoeia²⁴ is to have effect for the purposes of these provisions, which are modified accordingly²⁵.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 As to the meaning of 'business' see PARA 7 note 11 ante.

3 For the meaning of 'medicinal product' see PARA 7 ante.

4 Medicines Act 1968 s 65(1)(a).

5 For the meaning of 'practitioner' see PARA 7 note 10 ante.

6 Medicines Act 1968 s 65(1)(b).

7 See the text and notes 14-21 infra.

8 Medicines Act 1968 s 65(1). Where a notice has been published under s 65(7) (see the text to notes 22-25 infra), the references in s 65(1)(a), (b) to a particular name include a reference to an approved synonym: s 65(7).

9 Ibid s 65(2).

10 Ie in the circumstances specified in ibid s 65(1), (2): see the text and notes 1-9 supra.

11 As to the meaning of 'ingredient' see PARA 7 note 7 ante.

12 Medicines Act 1968 s 65(3).

13 Ibid s 67(2). Such a person is liable on summary conviction to a fine not exceeding the prescribed sum (s 67(4)(a) (amended by virtue of the Magistrates' Courts Act 1980 s 32(2)), or on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both (Medicines Act 1968 s 67(4)(b)). As to the prescribed sum see PARA 32 note 3 ante. A person charged with such an offence may in certain circumstances raise the defence that he purchased the article to which the charge relates under a warranty as to its quality: see s 122; and PARA 180 post. As to enforcement, prosecution, defences and related matters see PARA 176 et seq post.

14 The definition applies in relation to the sale or supply of a medicinal product which has been demanded, described in a prescription or offered or exposed for sale by or by express reference to a particular name: ibid s 65(4). Where a notice has been published under s 65(7) (see the text to notes 22-25 infra), references to a particular name include references to an approved synonym: s 65(7).

15 A current edition of a publication must be taken as it is for the time being in force (ie together with any amendments, additions and deletions made to it up to the time when the medicinal product in question is demanded, described in a prescription or offered or exposed for sale): ibid s 65(4), (6)(a). If it is an edition previous to the current edition of that publication, an edition must be taken as it was immediately before the time when it was superseded by a subsequent edition (ie together with any amendments, additions and deletions made up to that time): s 65(6)(b). Any monograph in an edition of a publication must be construed in accordance with any general monograph or notice or any appendix note or other explanatory material which is contained in that edition and is applicable to that monograph, and any reference in s 65 (as amended) to compliance with the standard specified in a monograph must be construed accordingly: s 65(6).

16 'Publication' means one of the following: the British Pharmacopoeia, the British Pharmaceutical Codex, the British Veterinary Codex and any compendium published under ibid Pt VII (ss 99-103) (as amended) (see PARA 149 et seq post), and, when a notice has been published under s 65(7) (see the text to notes 22-25 infra), the European Pharmacopoeia: s 65(4), (7).

17 'Current' means current at the time when the medicinal product in question is demanded, described in a prescription or offered or exposed for sale as mentioned in ibid s 65(1), (2) (see the text to notes 1-9 supra): s 65(4).

18 'The appropriate current monograph' means: (1) the monograph, if any, headed by that name in the current edition of the British Pharmacopoeia or, where a notice has been published under ibid s 65(7) (see the text to notes 22-25 infra), the monograph, if any, headed by that name or by a name for which it is an approved synonym in the current edition of the European Pharmacopoeia, or, if there is no such monograph, then the monograph, if any, headed by that name in the current edition of the British Pharmacopoeia (s 65(5)(a), (7)); or (2) if there is no such monograph, then the monograph, if any, headed by that name in the current edition of a compendium published under Pt VII (as amended) (see PARA 149 et seq post) (s 65(5)(b)); or (3) if there is no such monograph, then the monograph, if any, headed by that name in the current edition of the British Pharmaceutical Codex or the British Veterinary Codex (s 65(5)(c)). A name is taken to be an approved synonym for a name at the head of a monograph in the European Pharmacopoeia if by a notice published as mentioned in s 65(7) and not withdrawn by any subsequent notice so published, it has been declared to be approved by the Commission on Human Medicines as a synonym for that name: s 65(8) (amended by the Medicines (Advisory Bodies) Regulations 2005, SI 2005/1094, reg 8, Sch 1 para 13). As to the constitution of the Commission see PARA 13 ante.

19 Medicines Act 1968 s 65(4)(a). Where a notice has been published under s 65(7) (see the text to notes 22-25 infra), references to a particular name include references to an approved synonym: s 65(7).

20 Ibid s 65(4)(b). Where a notice has been published under s 65(7) (see the text to notes 22-25 infra), references to a particular name include references to an approved synonym: s 65(7).

21 Ibid s 65(4)(c).

22 For the meaning of 'the health ministers' see PARA 3 note 4 ante.

23 'The Gazette' means the London, Edinburgh and Belfast Gazettes: Medicines Act 1968 s 132(1).

24 The European Pharmacopoeia was prepared in pursuance of the Convention on the Elaboration of a European Pharmacopoeia (Strasbourg, 22 July 1964; TS 32 (1974); Cmnd 5763). An edition of the European Pharmacopoeia, if it is the current edition at the time in question, is to be taken as it is for the time being in force in the United Kingdom (ie together with any amendments, additions and deletions made to it which, by notice published as mentioned in the Medicines Act 1968 s 65(7), before the time when the medicinal product in question is demanded, described in a prescription or offered or exposed for sale, have been declared to have effect for the purposes of s 65 (as amended)): s 65(8)(a). If it is an edition previous to the current edition, an edition of the European Pharmacopoeia is to be taken as it was immediately before the time when it was superseded by a subsequent edition in force in the United Kingdom (ie together with any amendments, additions and deletions made to it which, by notice so published before that time, had been declared so to have effect): s 65(8)(b). For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

25 Ibid s 65(7). Many such notices have been published: see eg those published in the London Gazette for 27 February 2004, 25 May 2004, 1 November 2004, 25 November 2004, 7 March 2005, 27 May 2005.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(8) QUALITY AND STANDARDS; COMPENDIA/(ii) The British Pharmacopoeia and other Compendia/149. The British Pharmacopoeia and other publications.

(ii) The British Pharmacopoeia and other Compendia

149. The British Pharmacopoeia and other publications.

The appropriate body¹ must, at any such time as may be determined², prepare or cause to be prepared a new edition³ of the British Pharmacopoeia containing such relevant information⁴ as may be determined relating to substances⁵ and articles⁶ (whether medicinal products⁷ or not) which are or may be used in the practice of medicine (other than veterinary medicine), surgery (other than veterinary surgery), dentistry or midwifery⁸, and substances and articles used in the manufacture of such substances or articles⁹. The appropriate body may also, at any such time as may be determined, prepare or cause to be prepared a compendium other than the British Pharmacopoeia containing such relevant information relating to such substances or articles or any class of them as may be determined, or a new edition of any such compendium¹⁰, and a compendium containing such relevant information relating to substances or articles (whether veterinary drugs¹¹ or not) which are or may be used in the practice of veterinary medicine or veterinary surgery, and substances and articles used in the manufacture of such substances or articles, as may be determined, or a new edition of any such compendium¹².

Where any such new edition or compendium has been prepared, then, on the recommendation of the Commission on Human Medicines¹³, the health ministers or, in the case of a compendium relating to veterinary substances or articles, the agriculture ministers¹⁴, must cause it to be published¹⁵ and, in accordance with arrangements made by the appropriate ministers¹⁶, copies must be made available for sale to the public¹⁷.

The appropriate body must also, whenever directed by the Commission, prepare or cause to be prepared other publications containing such relevant information as may be determined relating to the substances and articles referred to above¹⁸, and, on the recommendation of the Commission, the health ministers or agriculture ministers may cause such a publication to be published and may arrange for it to be available for sale to the public or to be otherwise distributed as they may determine¹⁹.

The health ministers may publish any amendment of the British Pharmacopoeia or of any such compendium which in their opinion is necessary for the purpose of giving effect to the Convention on the Elaboration of a European Pharmacopoeia²⁰.

1 In the Medicines Act 1968 Pt VII (ss 98-103) (as amended), 'the appropriate body', in relation to any work falling to be prepared under Pt VII (as amended), means the committee (if any) established under s 4 (see PARA 15 ante) whose functions consist of or include the preparation of that work or, if for the time being there is no such committee, means the Commission on Human Medicines: s 99(7). The British Pharmacopoeia Commission has been established for these purposes by the Medicines (British Pharmacopoeia Commission) Order 1970, SI 1970/1256 (amended by SI 1982/1335). As to the Commission on Human Medicines see PARA 13 et seq ante.

2 Anything falling to be determined for the purposes of the Medicines Act 1968 s 99(1), (3) (see the text to notes 10-12 infra), except where the appropriate body is the Commission on Human Medicines, must be determined in accordance with directions given by the Commission (s 99(5)(a)), or where the appropriate body is the Commission, must be determined by the Commission (s 99(5)(b)).

3 The provisions of *ibid* s 99(1)-(6) apply to amendments as they apply to new editions: s 102(1). 'Amendment' includes addition and deletion: s 102(7).

4 'Relevant information' in relation to any substances or articles means any information consisting of descriptions of, standards for, or notes or other matter relating to, those substances or articles: *ibid* ss 99(7), 101(4).

5 For the meaning of 'substance' see *PARA 7* note 1 *ante*.

6 Medicines Act 1968 s 99(1).

7 For the meaning of 'medicinal product' see *PARA 7* *ante*.

8 Medicines Act 1968 s 99(2)(a). As to the medical, dentistry and midwifery professions see *MEDICAL PROFESSIONS*. As to the veterinary profession see *ANIMALS* vol 2 (2008) *PARA 1126 et seq*.

9 *Ibid* s 99(2)(b). As to the meaning of 'manufacture' see *PARA 7* note 2 *ante*.

10 *Ibid* s 99(3)(a). See also note 2 *supra*.

11 For the meaning of 'veterinary drug' see *PARA 3* note 7 *ante*.

12 Medicines Act 1968 s 99(3)(b), (4). See also note 2 *supra*.

13 For the meaning of 'the health ministers' see *PARA 3* note 4 *ante*.

14 For the meaning of 'the agriculture ministers' see *PARA 3* note 5 *ante*.

15 Medicines Act 1968 s 99(6) (amended by the Statute Law (Repeals) Act 2004). The obligation to publish the British Pharmacopoeia was previously imposed on, and the rights therein were vested in, the General Medical Council: Medical Act 1956 s 47 (repealed). As from 1 February 1978 the copyright was assigned to the Crown and the Council's obligation to publish ceased: Medicines Act 1968 s 98 (repealed); Medicines Act 1968 (Commencement No 7) Order 1977, SI 1977/2128. As to Crown copyright see *COPYRIGHT, DESIGN RIGHT AND RELATED RIGHTS* vol 9(2) (2006 Reissue) *PARA 144 et seq*.

16 'The appropriate ministers', in relation to any subject matter required or authorised to be published under the Medicines Act 1968 Pt VII (as amended), means the ministers causing it to be published: s 102(7).

17 *Ibid* s 102(4)(a). Every such copy (and every copy of a list prepared under s 100: see *PARA 150 post*) must specify the date on which the subject matter contained in it is to take effect, and the appropriate ministers must give notice of that date by notices published not less than 21 days before that date in the Gazette: s 102(5). Any document purporting to be such a copy, and to be printed by a person named in the relevant Gazette notice as being a person authorised by those ministers to print copies of the subject matter contained in it, must be received in evidence as being a true copy of that subject matter and is evidence of the date on which that subject matter came into operation: s 102(6). For the meaning of 'the Gazette' see *PARA 148* note 23 *ante*. For the meaning of 'person' see *PARA 21* note 7 *ante*.

18 *Ibid* s 101(1). In relation to a journal or other periodical, a direction under s 101(1) or a recommendation under s 101(2) (see the text to note 19 *infra*) may be given in relation to a particular issue (s 101(3)(a)) or so as to have effect in relation to successive issues while the direction or recommendation remains in force (s 101(3)(b)).

19 *Ibid* s 101(2). See also note 18 *supra*.

20 *Ibid* s 102(2). As to the Convention see *PARA 148* note 24 *ante*. In accordance with arrangements made by the appropriate ministers, copies of any such amendment must be made available for sale to the public: s 102(4)(c). See also s 102(5), (6); and note 17 *supra*.

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150. Lists of names of substances and articles.

The appropriate body¹ must² prepare or cause to be prepared a list of names suitable to be used as the names of the specified substances³ or articles⁴ and to be placed at the head of monographs relating to those substances or articles in any edition of the British Pharmacopoeia or any other compendium or edition of a compendium⁵.

Where any such list has been prepared, the ministers⁶, on the recommendation of the Commission on Human Medicines, must cause it to be published⁷, and, in accordance with arrangements made by the Commission, copies of any such list must be made available for sale to the public⁸. These provisions⁹ have effect in relation to the preparation and publication of amendments¹⁰ of any list so published as they have effect in relation to the preparation and publication of any such list¹¹.

1 For the meaning of 'the appropriate body' see PARA 149 note 1 ante.

2 Ie whenever, if the appropriate body is a committee established under the Medicines Act 1968 s 4 (see PARA 15 ante), it is directed by the Commission on Human Medicines to do so (s 100(1)(a)) or, if that body is the Commission, the Commission considers it expedient to do so (s 100(1)(b)). As to the British Pharmacopoeia Commission established for these purposes see PARA 149 note 1 ante. As to the Commission on Human Medicines see PARA 13 et seq ante.

3 For the meaning of 'substance' see PARA 7 note 1 ante.

4 Ie the substances and articles to which the Medicines Act 1968 s 99(1), (3)(b) apply: see PARA 149 ante.

5 Ibid s 100(1). As to the preparation of the British Pharmacopoeia and other compendia see PARA 149 ante. A list may be so prepared and published in substitution for, and so as to supersede, any such list previously prepared and published: s 100(3).

6 For the meaning of 'the ministers' see PARA 3 note 3 ante.

7 Medicines Act 1968 s 100(2).

8 Ibid s 102(4)(b). See also s 102(5), (6); and PARA 149 note 17 ante.

9 Ie ibid s 100.

10 For the meaning of 'amendment' see PARA 149 note 3 ante.

11 Medicines Act 1968 s 102(3).

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151. Construction of references to specified publications.

Where any licence or certificate¹ refers to a specified publication² but not to a particular edition of it, then, for the purpose of determining whether anything done³ is done in accordance with the licence or certificate, the reference is to be construed, unless the licence or certificate otherwise expressly provides, as a reference to the current edition⁴ as then in force⁵.

Where under any enactment⁶ there is power, called 'the primary power'⁷, to make any regulations, rules, order, list or other instrument which is to have effect by virtue of or for the purposes of that enactment, and an instrument made in the exercise of that power⁸ could be made so as to refer to the current edition of a specified publication as in force at the time when the instrument is made⁹ but could not, apart from this provision, be made so as to refer to the current edition as in force at a subsequent time¹⁰, then, unless the enactment otherwise expressly provides, the power may be exercised so as to refer to the current edition as in force at such time¹¹ as may be specified in, or determined in accordance with, the instrument¹². Where the primary power includes power to vary instruments made in the exercise of the primary power, this provision has effect in relation to any exercise of the power to vary any such instrument¹³ as it has effect in relation to any exercise of the primary power¹⁴.

1 le any licence granted or certificate issued under the Medicines Act 1968 Pt II (ss 6-50) (as amended): see PARAS 43 et seq, 130 et seq ante.

2 'Specified publication' means the European Pharmacopoeia, the British Pharmacopoeia, the British Pharmaceutical Codex, the International Pharmacopoeia, the Cumulative List of Recommended International Nonproprietary Names, the British Veterinary Codex, the British National Formulary, the Dental Practitioners' Formulary, any compendium prepared and published under *ibid* s 99(3), (6) (see PARA 149 ante), and any list of names prepared and published under s 100 (see PARA 150 ante): s 103(1) (amended by the Health and Medicines Act 1988 s 22(1)). Regulations and orders made under the Medicines Act 1968 before 15 November 1988 are to be construed as if the references in s 103(1) (as amended) to the International Pharmacopoeia and the Cumulative List of Recommended International Nonproprietary Names had been in that provision when the regulations or orders were made, except where the term 'specified publication' is used in such orders or regulations: Health and Medicines Act 1988 s 22(2). References in such orders or regulations made before that date to International Nonproprietary Names are to be construed as references to the Cumulative List: s 22(3).

3 le anything done at a time when the licence or certificate is in force: Medicines Act 1968 s 103(2).

4 Any reference to the current edition of a specified publication as in force at a particular time is a reference to the edition of it in force, under whatever title, at that time together with any amendments, additions and deletions made to it up to that time: *ibid* s 103(5) (amended by the Health and Medicines Act 1988 s 22(6)).

5 Medicines Act 1968 s 103(2).

6 'Enactment' includes an enactment of the Northern Ireland Parliament (*ibid* s 134(4)) and, except in so far as the context otherwise requires, any reference to an enactment must be construed as a reference to that enactment as amended or extended by or under any other enactment, including the Medicines Act 1968 (s 132(6)); but it does not include an enactment comprised in, or in an instrument made under, an Act of the Scottish Parliament (Interpretation Act 1978 s 5, Sch 1). In this context, it includes an enactment whenever passed: Medicines Act 1968 s 103(3) (amended by the Health and Medicines Act 1988 s 22(4)). As to the Northern Ireland Assembly and the Scottish Parliament see CONSTITUTIONAL LAW AND HUMAN RIGHTS.

7 Medicines Act 1968 s 103(4).

8 Any reference to making an instrument in the exercise of a power conferred by an enactment includes a reference to issuing or approving such an instrument: *ibid* s 103(5).

9 Ibid s 103(3)(a).

10 Ibid s 103(3)(b).

11 Is whether before, at or after the time when the instrument was made: *ibid* s 103(3) (as amended: see note 6 *supra*).

12 Ibid s 103(3).

13 Is whether the instrument was made before, or is made after, the passing of the Medicines Act 1968: s 103(4).

14 Ibid s 103(4).

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(9) LABELLING, MARKING AND LEAFLETS

152. Labelling and marking of containers and packages.

The appropriate ministers¹ may make regulations² imposing such requirements³ as they consider necessary or expedient for any of the following purposes with respect to the labelling⁴ of containers of medicinal products⁵ and of packages of such products⁶ and the display of distinctive marks on such containers and packages⁷: (1) securing that medicinal products are correctly described and readily identifiable⁸; (2) securing that any appropriate warning or other appropriate information or instruction is given, and that false or misleading information is not given, with respect to medicinal products⁹; and (3) promoting safety¹⁰ in relation to medicinal products¹¹.

No person¹² may, in the course of a business¹³ carried on by him, sell or supply, or have in his possession for the purpose of sale or supply, any medicinal product in such circumstances as to contravene¹⁴ any requirements imposed by such regulations which are applicable to that product¹⁵. The regulations may provide that any person who contravenes this provision or the provisions of the regulations is guilty of an offence¹⁶. Similarly, no person may, in the course of a business carried on by him, sell or supply, or have in his possession for the purpose of sale or supply, a medicinal product of any description contained in a container or package which is labelled or marked in such a way that the container or package falsely describes the product¹⁷ or is likely to mislead¹⁸ as to the nature or quality of the product or as to the uses or effects of medicinal products of that description¹⁹. Subject to the provisions relating to contravention due to the default of another person and warranty as a defence²⁰, any person who contravenes this provision is guilty of an offence²¹.

1 For the meaning of 'the appropriate ministers' see PARA 3 ante.

2 Without prejudice to the application of the Medicines Act 1968 s 129(5) (see PARA 5 ante), any such power to make regulations may be exercised so as to impose requirements either in relation to medicinal products generally or in relation to medicinal products of a particular description, or falling within a particular class, specified in the regulations: s 91(3). For the meaning of 'medicinal product' see PARA 7 ante. As to the description of medicinal products see PARA 7 note 33 ante. Before making any such regulations the ministers must consult appropriate organisations: see s 129(6); and PARA 5 ante. As to the making of regulations see PARA 5 ante. As to the information to be made available to ministers before they make regulations see *R (on the application of National Association of Health Stores) v Secretary of State for Health* [2005] EWCA Civ 154, [2005] All ER (D) 324 (Feb).

3 'Requirements' includes restrictions: Medicines Act 1968 s 91(4).

4 'Labelling' means affixing to or otherwise displaying on a container or package of medicinal products, a notice describing or otherwise relating to its contents; and 'label' has a corresponding meaning: *ibid* s 132(1). 'Container', in relation to a medicinal product, means the bottle, jar, box, packet or other receptacle which contains or is to contain the medicinal product, not being a capsule, cachet or other article in which the product is to be administered; and, where any such receptacle is or is to be contained in another such receptacle, includes the former but not the latter: s 132(1). As to the meaning of 'administer' see PARA 7 note 2 ante. 'Package', in relation to any medicinal products, means any box, packet or other article in which one or more containers of the products are or are to be enclosed; and, where any such box, packet or other article is or is to be itself enclosed in one or more other boxes, packets or other articles, includes each of the boxes, packets or articles in question: s 132(1).

5 Ibid s 85(1)(a). The provisions of s 85(1)-(4) apply also to animal feeding stuffs in which medicinal products have been incorporated: see s 90(1); and AGRICULTURAL PRODUCTION AND MARKETING vol 1 (2008) PARA 996 et seq. For the meaning of 'animal feeding stuffs' see PARA 7 note 2 ante.

6 Ibid s 85(1)(b).

7 Ibid s 85(1)(c). As to the regulations that have been made see the Medicines (Labelling) Regulations 1976, SI 1976/1726 (amended by SI 1977/996; SI 1977/2168; SI 1978/41; SI 1978/1140; SI 1981/1791; SI 1983/1729; SI 1985/1588; SI 1985/2008; SI 1988/1009; SI 1989/1183; SI 1992/3273; SI 1994/104; SI 1994/3142; SI 1994/3144; SI 1996/2194; SI 2002/236; SI 2004/1031; SI 2005/2753; SI 2005/2754; and by virtue of the Criminal Justice Act 1988 s 51); the Medicines (Labelling and Advertising to the Public) Regulations 1978, SI 1978/41 (amended by SI 1994/1932; SI 2002/880; SI 2003/1590; SI 2004/1771; and by virtue of the Criminal Justice Act 1988 s 51); the Medicines (Contact Lens Fluids and Other Substances) (Labelling) Regulations 1979, SI 1979/1759 (amended by SI 1981/1689; and by virtue of the Criminal Justice Act 1988 s 51); the Medicines (Labelling of Medicinal Products for Incorporation in Animal Feeding Stuffs and of Medicated Animal Feeding Stuffs) Regulations 1988, SI 1988/1009 (amended by SI 1994/3142; SI 1998/1048; SI 1996/2194; and by virtue of the Criminal Justice Act 1988 s 51); and the Medicines (Advertising) Regulations 1994, SI 1994/1932 (amended by SI 1994/3144; SI 1996/1552; SI 1999/267; SI 2002/236; SI 2003/2321; SI 2004/1480; SI 2005/2787). As to the labelling of products for the purposes of the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144 (as amended) see PARA 23 note 5 ante; and as to the labelling of products for the purposes of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142 (as amended) see PARAS 34, 38 ante.

8 Medicines Act 1968 s 85(2)(a).

9 Ibid s 85(2)(b).

10 As to considerations of safety see PARA 15 note 10 ante.

11 Medicines Act 1968 s 85(2)(c).

12 For the meaning of 'person' see PARA 21 note 7 ante.

13 As to the meaning of 'business' see PARA 7 note 11 ante.

14 For the meaning of 'contravene' see PARA 6 note 21 ante. In so far as any such requirements relate to the labelling or marking of containers, a person who in the course of a business carried on by him sells or supplies a medicinal product to which the requirements are applicable without its being enclosed in a container is taken, except in so far as the regulations otherwise provide, to contravene those requirements as if he had sold or supplied it in a container not complying with them: Medicines Act 1968 s 85(4).

15 Ibid s 85(3). In relation to this offence, certain presumptions apply in respect of a person having a medicinal product in his possession for the purpose of sale or supply: see s 126(2), (3); and PARA 184 post.

16 Ibid s 91(2). See also the regulations mentioned in note 7 supra. Such a person is liable on summary conviction to a fine not exceeding the prescribed sum or such lesser sum as may be specified in the regulations (s 91(2)(a) (amended by virtue of the Magistrates' Courts Act 1980 s 32(2))) or, if the regulations so provide, on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both (Medicines Act 1968 s 91(2)(b)). As to the prescribed sum see PARA 32 note 3 ante. As to enforcement, prosecution, defences and related matters see PARA 176 et seq post.

17 Ibid s 85(5)(a). In relation to this offence, certain presumptions apply in respect of a person having a medicinal product in his possession for the purpose of sale or supply: see s 126(2), (3); and PARA 184 post.

18 A document, advertisement or representation is to be taken to be likely to mislead as to the uses or effects of medicinal products of a particular description if it is likely to mislead as to: (1) any purposes for which such medicinal products can with reasonable safety be used (ibid s 130(10)(a)); (2) any purposes for which they cannot be so used (s 130(10)(b)); and (3) any effects which such products, when used, or when used in any particular way referred to in the document, advertisement or representation, produce or are intended to produce (s 130(10)(c)).

19 Ibid s 85(5)(b).

20 Ie ibid ss 121, 122: see PARAS 179-180 post.

21 Ibid s 91(1). Such a person is liable on summary conviction to a fine not exceeding the prescribed sum (s 91(1)(a) (amended by virtue of the Magistrates' Courts Act 1980 s 32(2))) or on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both (Medicines Act 1968 s 91(1)(b)).

UPDATE

152 Labelling and marking of containers and packages

NOTE 7--SI 1976/1726 amended, SI 1988/1009 revoked: SI 2005/2745.

NOTE 8--SI 1994/3142 revoked: SI 2005/2745.

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153. Leaflets.

The appropriate ministers¹ may make regulations² imposing such requirements³ as, for any of the purposes specified in the provisions concerned with labelling and marking⁴, they consider necessary or expedient with respect to leaflets⁵ relating to medicinal products which are supplied, or are intended to be supplied, with the products, whether by being enclosed in containers⁶ or packages⁷ of the products or otherwise⁸.

No person, in the course of a business carried on by him, may supply with any medicinal product, or have in his possession for the purpose of so supplying, a leaflet which contravenes any requirements imposed by regulations which are applicable to the leaflet⁹. Regulations may provide that any person contravening this provision or the regulations is guilty of an offence¹⁰. Similarly, no person, in the course of a business carried on by him, may supply with a medicinal product of any description¹¹, or have in his possession for the purpose of so supplying, a leaflet which falsely describes the product¹² or which is likely to mislead¹³ as to the nature or quality of the product or as to the uses or effects of medicinal products of that description¹⁴. Subject to the provisions relating to contravention due to the default of another person and warranty as a defence, any person who contravenes this provision is guilty of an offence¹⁵.

1 For the meaning of 'the appropriate ministers' see PARA 3 ante.

2 Without prejudice to the application of the Medicines Act 1968 s 129(5) (see PARA 5 ante), any such power to make regulations may be exercised so as to impose requirements either in relation to medicinal products generally or in relation to medicinal products of a particular description, or falling within a particular class, specified in the regulations: s 91(3). For the meaning of 'medicinal product' see PARA 7 ante. Before making any such regulations the ministers must consult appropriate organisations: see s 129(6); and PARA 5 ante. As to the making of regulations see PARA 5 ante. As to the information to be made available to ministers before they make regulations see *R (on the application of National Association of Health Stores) v Secretary of State for Health* [2005] EWCA Civ 154, [2005] All ER (D) 324 (Feb).

3 For the meaning of 'requirements' see PARA 152 note 3 ante.

4 ie the purposes specified in the Medicines Act 1968 s 85(2): see PARA 152 heads (1)-(3) ante.

5 'Leaflet' includes any written information: *ibid* s 132(1).

6 For the meaning of 'container' see PARA 152 note 4 ante.

7 For the meaning of 'package' see PARA 152 note 4 ante.

8 Medicines Act 1968 s 86(1). No person may, in the course of a business carried on by him, supply a product to which European Parliament and Council Directive EC 2001/83 (OJ L311, 28.11.2001, p 67) on the Community code relating to medicinal products for human use (as amended) applies, unless a leaflet enclosed in, or supplied with, the container or package of the product or the container or package itself contains the particulars which a leaflet relating to the product is required by regulations under the Medicines Act 1968 s 86(1) to contain, and does so in the manner required by such regulations: s 86(4) (added by the Medicines Act 1968 (Amendment) (No 2) Regulations, SI 1994/276, reg 7(1); and amended by the Medicines (Codification Amendments Etc) Regulations 2002, SI 2002/236, reg 2(a)(vi)). Subject to the provisions relating to contravention due to the default of another person and warranty as a defence (see the Medicines Act 1968 ss 121, 122; and PARAS 179-180 post), any person who contravenes this provision is guilty of an offence: s 91(1) (amended by the Medicines Act 1968 (Amendment) (No 2) Regulations, SI 1994/276, reg 8). As to the penalty for such an offence see the Medicines Act 1968 s 91(1)(a), (b) (s 91(1)(a) as amended); and note 15 infra. For the meaning of 'person' see PARA 21 note 7 ante. As to the meaning of 'business' see PARA 7 note 11 ante. For the meaning of 'contravene' see PARA 6 note 21 ante. The provisions of s 86(1) apply also to animal feeding stuffs in which medicinal products have been incorporated: see s 90(1); and AGRICULTURAL PRODUCTION AND MARKETING vol 1 (2008) PARA 996 et seq. For the meaning of 'animal feeding stuffs' see PARA 7 note 2 ante.

As to the regulations that have been made under s 86 (as amended) see the Medicines (Labelling) Regulations 1976, SI 1976/1726 (amended by SI 1977/996; SI 1977/2168; SI 1978/41; SI 1978/1140; SI 1981/1791; SI 1983/1729; SI 1985/1588; SI 1985/2008; SI 1988/1009; SI 1989/1183; SI 1992/3273; SI 1994/104; SI 1994/3142; SI 1994/3144; SI 1996/2194; SI 2002/236; SI 2004/1031; SI 2005/2753; SI 2005/2754; and by virtue of the Criminal Justice Act 1988 s 51); the Medicines (Leaflets) Regulations 1977, SI 1977/1055 (amended by SI 1992/3274; SI 1994/104; SI 1994/3144; SI 2005/2753 and by virtue of the Criminal Justice Act 1988 s 51); the Medicines (Labelling and Advertising to the Public) Regulations 1978, SI 1978/41 (amended by SI 1994/1932; SI 2002/880; SI 2003/1590; SI 2004/1771; and by virtue of the Criminal Justice Act 1988 s 51); the Medicines (Contact Lens Fluids and Other Substances) (Labelling) Regulations 1979/1759 (amended by SI 1981/1689; and by virtue of the Criminal Justice Act 1988 s 51); the Medicines (Labelling of Medicinal Products for Incorporation in Animal Feeding Stuffs and of Medicated Animal Feeding Stuffs) Regulations 1988, SI 1988/1009 (amended by SI 1994/3142; SI 1998/1048; SI 1996/2194; and by virtue of the Criminal Justice Act 1988 s 51); and the Medicines (Advertising) Regulations 1994, SI 1994/1932 (amended by SI 1994/3144; SI 1996/1552; SI 1999/267; SI 2002/236; SI 2003/2321; SI 2004/1480; SI 2005/2787). As to the provisions relating to leaflets for the purposes of the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144 (as amended) see PARA 23 note 5 ante. The Medicines Act 1968 s 86 (as amended) applies for the purposes of the Marketing Authorisations for Veterinary Medicinal Products Regulations 1994, SI 1994/3142 (as amended): see PARA 34 ante.

9 Medicines Act 1968 s 86(2). In relation to this offence, certain presumptions apply in respect of a person having a leaflet in his possession: see s 126(4); and PARA 184 post. The provisions of s 86(2) apply also to animal feeding stuffs in which medicinal products have been incorporated: see s 90(1); and AGRICULTURAL PRODUCTION AND MARKETING vol 1 (2008) PARA 996 et seq.

10 Ibid s 91(2). See also the regulations mentioned in note 8 supra. Such a person is liable on summary conviction to a fine not exceeding the prescribed sum or such lesser sum as may be specified in the regulations (s 91(2)(a) (amended by virtue of the Magistrates' Courts Act 1980 s 32(2))) or, if the regulations so provide, on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both (Medicines Act 1968 s 91(2)(b)). As to the prescribed sum see PARA 32 note 3 ante. As to enforcement, prosecution, defences and related matters see PARA 176 et seq post.

11 As to the description of medicinal products see PARA 7 note 33 ante.

12 Medicines Act 1968 s 86(3)(a). In relation to this offence, certain presumptions apply in respect of a person having a leaflet in his possession: see s 126(4); and PARA 184 post.

13 As to the meaning of 'likely to mislead' in relation to a document, advertisement or representation see PARA 152 note 18 ante.

14 Medicines Act 1968 s 86(3)(b).

15 Ibid s 91(1). Such a person is liable on summary conviction to a fine not exceeding the prescribed sum (s 91(1)(a) (amended by virtue of the Magistrates' Courts Act 1980 s 32(2))) or on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both (Medicines Act 1968 s 91(1)(b)).

UPDATE

153 Leaflets

NOTE 8--SI 1976/1726 amended, SI 1988/1009, SI 1994/1342 revoked: SI 2005/2745.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(9) LABELLING, MARKING AND LEAFLETS/154. Containers.

154. Containers.

The appropriate ministers¹ may make regulations² prohibiting the sale or supply of medicinal products otherwise than in containers³ which comply with such requirements⁴ as those ministers consider necessary or expedient for any of the purposes specified in the provisions concerned with labelling and marking⁵, or for the purpose of preserving the quality of the products, and, in particular, may by the regulations require such containers to be of such strength, to be made of such materials, and to be of such shapes or patterns, as may be prescribed⁶.

No person⁷, in the course of a business⁸ carried on by him, may sell or supply, or have in his possession for the purpose of sale or supply, any medicinal product in such circumstances as to contravene⁹ any requirements imposed by regulations which are applicable to that product¹⁰. Regulations may provide that any person who contravenes this provision or the regulations is guilty of an offence¹¹.

1 For the meaning of 'the appropriate ministers' see PARA 3 ante.

2 Without prejudice to the application of the Medicines Act 1968 s 129(5) (see PARA 5 ante), any such power to make regulations may be exercised so as to impose requirements either in relation to medicinal products generally or in relation to medicinal products of a particular description, or falling within a particular class, specified in the regulations: s 91(3). For the meaning of 'medicinal product' see PARA 7 ante. Before making any such regulations the ministers must consult appropriate organisations: see s 129(6); and PARA 5 ante. As to the making of regulations see PARA 5 ante. As to the information to be made available to ministers before they make regulations see *R (on the application of National Association of Health Stores) v Secretary of State for Health* [2005] EWCA Civ 154, [2005] All ER (D) 324 (Feb).

3 For the meaning of 'container' see PARA 152 note 4 ante.

4 For the meaning of 'requirements' see PARA 152 note 3 ante.

5 In the purposes specified in the Medicines Act 1968 s 85(2): see PARA 152 heads (1)-(3) ante.

6 Ibid s 87(1). For the meaning of 'prescribed' see PARA 56 note 3 ante. As to the regulations that have been made see the Medicines (Fluted Bottles) Regulations 1978, SI 1978/40 (amended by SI 1994/3142; SI 1994/3144; SI 2004/1031; and by virtue of the Criminal Justice Act 1988 s 51); and the Medicines (Child Safety) Regulations 2003, SI 2003/2317 (amended by SI 2004/1771; SI 2005/1520). The provisions of the Medicines Act 1968 s 87 apply also to animal feeding stuffs in which medicinal products have been incorporated: see s 90(1); and AGRICULTURAL PRODUCTION AND MARKETING vol 1 (2008) PARA 996 et seq. For the meaning of 'animal feeding stuffs' see PARA 7 note 2 ante.

7 For the meaning of 'person' see PARA 21 note 7 ante.

8 As to the meaning of 'business' see PARA 7 note 11 ante.

9 For the meaning of 'contravene' see PARA 6 note 21 ante.

10 Medicines Act 1968 s 87(2). In relation to this offence, certain presumptions apply in respect of a person having a medicinal product in his possession for the purpose of sale or supply: see s 126(2), (3); and PARA 184 post.

11 Ibid s 91(2). See also the regulations mentioned in note 6 supra. Such a person is liable on summary conviction to a fine not exceeding the prescribed sum or such lesser sum as may be specified in the regulations (s 91(2)(a) (amended by virtue of the Magistrates' Courts Act 1980 s 32(2))) or, if the regulations so provide, on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both (Medicines Act 1968 s 91(2)(b)). As to the prescribed sum see PARA 32 note 3 ante. As to enforcement, prosecution, defences and related matters see PARA 176 et seq post.

UPDATE

154 Containers

NOTE 6--SI 1978/40 amended: SI 2005/2745. SI 2003/2317 further amended: SI 2006/914, SI 2007/289, SI 2008/1162.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(9) LABELLING, MARKING AND LEAFLETS/155. Distinctive colours, shapes and markings.

155. Distinctive colours, shapes and markings.

Regulations¹ made by the appropriate ministers² may impose such requirements³ as those ministers consider necessary or expedient for any of the purposes specified in the provisions concerned with labelling and marking⁴ with respect to the colour of the products⁵, the shape of the products⁶ and distinctive marks to be displayed on the products⁷. Such regulations may provide that medicinal products of any such description⁸, or falling within any such class, as may be specified must not, except in such circumstances (if any) as may be specified, be of any such colour or shape, or display any such mark, as may be specified⁹.

No person¹⁰, in the course of a business¹¹ carried on by him, may sell or supply, or have in his possession for the purpose of sale or supply, any medicinal product which contravenes¹² any requirements imposed by such regulations¹³. The regulations may provide that any person who contravenes the regulations is guilty of an offence¹⁴.

1 Before making any such regulations the appropriate organisations must be consulted: see the Medicines Act 1968 s 129(6); and PARA 5 ante. As to the making of regulations see PARA 5 ante. As to the information to be made available to ministers before they make regulations see *R (on the application of National Association of Health Stores) v Secretary of State for Health* [2005] EWCA Civ 154, [2005] All ER (D) 324 (Feb).

2 For the meaning of 'the appropriate ministers' see PARA 3 ante.

3 For the meaning of 'requirements' see PARA 152 note 3 ante.

4 ie the purposes specified in the Medicines Act 1968 s 85(2); see PARA 152 heads (1)-(3) ante.

5 Ibid s 88(1)(a).

6 Ibid s 88(1)(b).

7 Ibid s 88(1)(c). As to the regulations that have been made see the Medicines (Child Safety) Regulations 2003, SI 2003/2317 (amended by SI 2004/1771; SI 2005/1520).

8 For the meaning of 'medicinal product' see PARA 7 ante. As to the description of medicinal products see PARA 7 note 33 ante.

9 Medicines Act 1968 s 88(2).

10 For the meaning of 'person' see PARA 21 note 7 ante.

11 As to the meaning of 'business' see PARA 7 note 11 ante.

12 For the meaning of 'contravene' see PARA 6 note 21 ante.

13 Medicines Act 1968 s 88(3). In relation to this offence, certain presumptions apply in respect of a person having a medicinal product in his possession for the purpose of sale or supply: see s 126(2), (3); and PARA 184 post.

14 Ibid s 91(2). Such a person is liable on summary conviction to a fine not exceeding the prescribed sum or such lesser sum as may be specified in the regulations (s 91(2)(a) (amended by virtue of the Magistrates' Courts Act 1980 s 32(2))) or, if the regulations so provide, on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both (Medicines Act 1968 s 91(2)(b)). As to the prescribed sum see PARA 32 note 3 ante. As to enforcement, prosecution, defences and related matters see PARA 176 et seq post.

UPDATE

155 Distinctive colours, shapes and markings

NOTE 7--SI 2003/2317 further amended: SI 2006/914, SI 2007/289, SI 2008/1162.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(9) LABELLING, MARKING AND LEAFLETS/156. Display of information on automatic machines.

156. Display of information on automatic machines.

Regulations¹ made by the appropriate ministers² may impose such requirements³ as they consider necessary or expedient with respect to the display on automatic machines of information relating to medicinal products⁴ offered or exposed for sale by means of such machines⁵. No person⁶ may offer or expose for sale any medicinal product by means of an automatic machine in such circumstances as to contravene⁷ any requirements imposed by such regulations which are applicable to that product⁸. The regulations may provide that any person who contravenes the regulations is guilty of an offence⁹.

1 Before making any such regulations the appropriate organisations must be consulted: see the Medicines Act 1968 s 129(6); and PARA 5 ante. As to the making of regulations see PARA 5 ante. As to the information to be made available to ministers before they make regulations see *R (on the application of National Association of Health Stores) v Secretary of State for Health* [2005] EWCA Civ 154, [2005] All ER (D) 324 (Feb).

2 For the meaning of 'the appropriate ministers' see PARA 3 ante.

3 For the meaning of 'requirements' see PARA 152 note 3 ante.

4 For the meaning of 'medicinal product' see PARA 7 ante.

5 Medicines Act 1968 s 89(1). At the date at which this volume states the law, no such regulations had been made. For other provisions regulating the sale of medicinal products from automatic machines see PARA 136 ante.

6 For the meaning of 'person' see PARA 21 note 7 ante.

7 For the meaning of 'contravene' see PARA 6 note 21 ante.

8 Medicines Act 1968 s 89(2).

9 Ibid s 91(2). Such a person is liable on summary conviction to a fine not exceeding the prescribed sum or such lesser sum as may be specified in the regulations (s 91(2)(a) (amended by virtue of the Magistrates' Courts Act 1980 s 32(2))) or, if the regulations so provide, on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both (Medicines Act 1968 s 91(2)(b)). As to the prescribed sum see PARA 32 note 3 ante. As to enforcement, prosecution, defences and related matters see PARA 176 et seq post.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(10) ADVERTISING/157. Meaning of 'advertisement'.

(10) ADVERTISING

157. Meaning of 'advertisement'.

For the purposes of the provisions of the Medicines Act 1968¹ regulating the promotion of sales of medicinal products², 'advertisement' includes every form of advertising, whether in a publication, or by the display of any notice, or by means of any catalogue, price list, letter (whether circular or addressed to a particular person), or other document or by words inscribed on any article, or by means of a photograph, film, sound recording or broadcast, or in any other way, and references to the issue of an advertisement are to be construed accordingly³. However, 'advertisement' does not include spoken words except words forming part of a sound recording or film sound track⁴, and words broadcast⁵; and, subject to certain exceptions⁶, the sale or supply, or offer or exposure for sale or supply, of a medicinal product in a labelled⁷ container⁸ or package⁹, or the supply, with a medicinal product of any description¹⁰, of a leaflet¹¹ relating solely to medicinal products of that description¹², is not to be taken to constitute the issue of an advertisement¹³.

1 Ie the Medicines Act 1968 Pt VI (ss 92-97) (as amended): see PARA 157 et seq post.

2 For the meaning of 'medicinal product' see PARA 7 ante.

3 Medicines Act 1968 s 92(1) (amended by the Copyright, Designs and Patents Act 1988 s 303(1), Sch 7 para 10(1), (2); and the Copyright and Related Rights Regulations 2003, SI 2003/2498, reg 2(1), Sch 1 Pt 2 para 19(a)). 'Film', 'sound recording', 'broadcast' and related expressions have the same meaning as in the Copyright, Designs and Patents Act 1988 Pt I (ss 1-179) (as amended) (see COPYRIGHT, DESIGN RIGHT AND RELATED RIGHTS): Medicines Act 1968 s 92(6) (substituted by the Copyright, Designs and Patents Act 1988 Sch 7 para 10(1), (4); and amended by the Copyright and Related Rights Regulations 2003, SI 2003/2498, reg 2(2), Sch 2).

4 Medicines Act 1968 s 92(2)(a) (amended by the Copyright, Designs and Patents Act 1988 s 303(2), Sch 8; and the Copyright and Related Rights Regulations 2003, SI 2003/2498, Sch 1 Pt 2 para 19(b)).

5 Medicines Act 1968 s 92(2)(b) (amended by the Copyright, Designs and Patents Act 1988 Sch 7 para 10(1), (2); and the Copyright and Related Rights Regulations 2003, SI 2003/2498, Sch 2).

6 Ie as provided by the Medicines Act 1968 s 95 (as amended): see PARA 158 post.

7 For the meaning of 'label' see PARA 152 note 4 ante.

8 For the meaning of 'container' see PARA 152 note 4 ante.

9 Medicines Act 1968 s 92(3)(a). For the meaning of 'package' see PARA 152 note 4 ante.

10 As to the description of medicinal products see PARA 7 note 33 ante.

11 As to the meaning of 'leaflet' see PARA 153 note 5 ante.

12 Medicines Act 1968 s 92(3)(b).

13 Ibid s 92(3).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(10) ADVERTISING/158. Regulation of advertisements and representations.

158. Regulation of advertisements and representations.

The appropriate ministers¹ may by regulations² prohibit³ any of the following:

- 134 (1) the issue of advertisements⁴ relating to medicinal products⁵ of a description, or falling within a class, specified in the regulations⁶;
- 135 (2) the issue of advertisements likely to lead to the use of any medicinal product, or any other substance⁷ or article, for the purpose of treating⁸ or preventing a disease⁹ so specified or for the purpose of diagnosis of a disease so specified or of ascertaining the existence, degree or extent of a physiological condition so specified or of permanently or temporarily preventing or otherwise interfering with the normal operation of a physiological function so specified, or for the purpose of artificially inducing a condition of body or mind so specified¹⁰;
- 136 (3) the issue of advertisements likely to lead to the use of medicinal products of a particular description or falling within a particular class so specified, or the use of any other substance or article of a description or class so specified, for any such purpose as is mentioned in head (2) above¹¹;
- 137 (4) the issue of advertisements relating to medicinal products and containing a word or phrase so specified as being a word or phrase which, in the opinion of the appropriate ministers, is likely to mislead¹² the public as to the nature or effects of the products or as to any condition of body or mind in connection with which the products might be used¹³.

Regulations under heads (2) to (4) above may also prohibit the making of any representation¹⁴ likely to lead to the use of a medicinal product or other substance or article to which the regulations apply for a purpose specified in the regulations in accordance with head (2) above¹⁵, or containing a word or phrase specified in the regulations in accordance with head (4) above¹⁶, if the representation is made in certain circumstances¹⁷.

The appropriate ministers may by regulations impose such requirements as, for any of certain purposes, they consider necessary or expedient with respect to: (a) the particulars which advertisements relating to medicinal products must contain¹⁸; (b) the form of any such advertisements¹⁹; and (c) in the case of advertisements by way of cinematograph films or television, the duration for which, and the manner in which, any part of such an advertisement which contains particulars of a specified description must be exhibited²⁰. Any such regulations may prohibit the use, in relation to medicinal products of a specified description, of advertisements of any particular specified kind²¹. The purposes referred to are: (i) securing that adequate information is given with respect to medicinal products²²; (ii) preventing the giving of misleading information with respect to such products²³; and (iii) promoting safety²⁴ in relation to such products²⁵.

Any such regulations may provide that any person who contravenes²⁶ them is guilty of an offence²⁷.

1 For the meaning of 'the appropriate ministers' see PARA 3 ante.

2 Before any such regulations are made, the appropriate organisations must be consulted: see the Medicines Act 1968 s 129(6); and PARA 5 ante. As to the making of regulations see PARA 5 ante. As to the information to be

made available to ministers before they make regulations see *R (on the application of National Association of Health Stores) v Secretary of State for Health* [2005] EWCA Civ 154, [2005] All ER (D) 324 (Feb).

3 Any prohibition imposed by such regulations may be a total prohibition or may be imposed subject to specified exceptions: Medicines Act 1968 s 95(5). As to the regulations that have been made under s 95 (as amended) see the Medicines (Advertising of Medicinal Products) Regulations 1975, SI 1975/298 (amended by virtue of the Criminal Justice Act 1988 s 51) (see PARA 161 post); the Medicines (Advertising of Medicinal Products) (No 2) Regulations 1975, SI 1975/1326 (amended by SI 1979/1760; SI 1994/1932; and by virtue of the Criminal Justice Act 1988 s 51) (see PARA 164 post); the Medicines (Labelling and Advertising to the Public) Regulations 1978, SI 1978/41 (amended by SI 1994/1932; SI 2002/880; SI 2003/1590; SI 2004/1771; and by virtue of the Criminal Justice Act 1988 s 51) (see PARA 162 post); the Medicines (Contact Lens Fluids and Other Substances) (Advertising and Miscellaneous Amendments) Regulations 1979, SI 1979/1760 (amended by SI 2005/848); the Medicines (Advertising) Regulations 1994, SI 1994/1932 (amended by SI 1994/3144; SI 1996/1552; SI 1999/267; SI 2002/236; SI 2003/2321; SI 2004/1480; SI 2005/2787) (see PARAS 163, 165 post); the Medicines (Advertising Amendments) Regulations 2005, SI 2005/2787.

4 For the meaning of 'advertisement', and as to references to 'the issue of an advertisement', see PARA 157 ante. The exemption of labels and leaflets from that definition (see the Medicines Act 1968 s 92(3)) does not have effect for the purposes of s 95(1)(b)-(d) (see heads (2)-(4) in the text): s 95(7).

5 For the meaning of 'medicinal product' see PARA 7 ante.

6 Medicines Act 1968 s 95(1)(a).

7 For the meaning of 'substance' see PARA 7 note 1 ante.

8 For the meaning of 'treatment' see PARA 8 note 1 ante.

9 As to the meaning 'disease' see PARA 8 note 2 ante.

10 Medicines Act 1968 s 95(1)(b). See also note 4 supra.

11 Ibid s 95(1)(c). See also note 4 supra.

12 As to the meaning of 'likely to mislead' in relation to a document, advertisement or representation see PARA 152 note 18 ante.

13 Medicines Act 1968 s 95(1)(d). See also note 4 supra.

14 'Representation' means any statement or undertaking, whether constituting a condition or a warranty or not, which consists of spoken words other than words falling within *ibid* s 92(2)(a), (b) (as amended) (see PARA 157 ante), and any reference to making a representation is to be construed accordingly: s 92(5). As to conditions and warranties see CONTRACT.

15 *Ie* in accordance with *ibid* s 95(1)(b): see head (2) in the text.

16 *Ie* in accordance with *ibid* s 95(1)(d): see head (4) in the text.

17 *Ibid* s 95(2). These circumstances arise if the representation: (1) is made in connection with the sale or supply, or offer for sale or supply, of a medicinal product or other substance or article to which the regulations apply (s 95(2)(a)); or (2) is made to a person for the purpose of inducing him to purchase such a medicinal product, substance or article from a person selling by retail medicinal products or other substances or articles to which the regulations apply (s 95(2)(b)); or (3) in the case of medicinal products of a description to which the regulations apply, is made to a practitioner for the purpose of inducing him to prescribe or supply medicinal products of that description or is made to a patient or client of a practitioner for the purpose of inducing him to request the practitioner to prescribe medicinal products of that description (s 95(2)(c)). For the meaning of 'person' see PARA 21 note 7 ante. As to references to retail sale and selling by retail see PARA 7 note 12 ante. For the meaning of 'practitioner' see PARA 7 note 10 ante.

18 *Ibid* s 95(3)(a).

19 *Ibid* s 95(3)(b).

20 *Ibid* s 95(3)(c).

21 *Ibid* s 95(3).

22 *Ibid* s 95(4)(a).

23 Ibid s 95(4)(b).

24 As to considerations of safety see PARA 15 note 10 ante.

25 Medicines Act 1968 s 95(4)(c).

26 For the meaning of 'contravene' see PARA 6 note 21 ante.

27 Medicines Act 1968 s 95(6). See also the regulations referred to in note 3 supra. The regulations may provide that any person who is guilty of such an offence is liable on summary conviction to a fine not exceeding the prescribed sum or such lesser sum as may be specified in the regulations (s 95(6)(a) (amended by the Magistrates' Courts Act 1980 s 32(2)), or, if the regulations so provide, on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both (Medicines Act 1968 s 95(6)(b)). As to the prescribed sum see PARA 32 note 3 ante. As to enforcement, prosecution, defences and related matters see PARA 176 et seq post. A defence is available in certain circumstances where the person charged proves that his contravention was due to the default of another person: see s 121; and PARA 179 post.

UPDATE

158 Regulation of advertisements and representations

NOTE 3--SI 1979/1760 further amended: SI 2007/3101.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(10) ADVERTISING/159. False or misleading advertisements and representations.

159. False or misleading advertisements and representations.

Any person¹ who, being a commercially interested party², or at the request or with the consent of a commercially interested party³, issues, or causes another person to issue, a false or misleading advertisement⁴ relating to medicinal products of any description, is guilty of an offence⁵.

Where a licence⁶ is in force which is applicable to medicinal products of a particular description, and, in accordance with the provisions of the licence, the purposes for which medicinal products of that description may be recommended to be used are limited to those specified in the licence, any person who, being a commercially interested party, or at the request or with the consent of a commercially interested party, issues, or causes another person to issue, an advertisement relating to medicinal products of that description which consists of or includes unauthorised recommendations⁷, is guilty of an offence⁸.

Any person who in the course of a relevant business⁹ carried on by him, or while acting on behalf of a person carrying on such a business, makes a false or misleading representation¹⁰ relating to a medicinal product in connection with the sale or offer for sale of that product, is guilty of an offence¹¹; and any person who, in the course of such a business or while acting on behalf of a person carrying on such a business, makes a false or misleading representation relating to medicinal products of a particular description to a practitioner¹² for the purpose of inducing him to prescribe or supply medicinal products of that description¹³, or to a patient or client of a practitioner for the purpose of inducing him to request the practitioner to prescribe medicinal products of that description¹⁴, or to a person for the purpose of inducing him to purchase medicinal products of that description from a person selling them by retail¹⁵, is guilty of an offence¹⁶.

Where a licence is in force which is applicable to medicinal products of a particular description, and, in accordance with the provisions of the licence, the purposes for which medicinal products of that description may be recommended to be used are limited to those specified in the licence, any person who, in the course of a relevant business carried on by him, or while acting on behalf of a person carrying on such a business, in connection with the sale, or offer for sale, of a medicinal product of the description in question, makes a representation relating to the product which consists of or includes unauthorised recommendations¹⁷, or makes a representation relating to medicinal products of that description for any of the specified purposes¹⁸ which consists of or includes unauthorised recommendations¹⁹, is guilty of an offence²⁰.

Any person guilty of any such offence is liable to a penalty²¹.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 'Commercially interested party', in relation to medicinal products of any description, means any person who: (1) is the holder of a licence under the Medicines Act 1968 Pt II (ss 6-50) (as amended) (see PARA 42 et seq ante), which is applicable to medicinal products of that description (s 92(4)(a)); or (2) not being the holder of such a licence, is a person who, in the course of a business carried on by him, is engaged, in relation to medicinal products of that description, in any such activities as are mentioned in s 7(2) or s 7(3) (see PARA 44 ante) or s 8(3) or s 8(3A) (as added) (see PARA 47 ante) (s 92(4)(b) (amended by the Medicines Act 1968 (Amendment) Regulations 1993, SI 1993/834, reg 7)); or (3) sells by retail any medicinal products of that description in the course of a business carried on by him (Medicines Act 1968 s 92(4)(c)). As to references to the holder of a licence see PARA 66 note 5 ante. For the meaning of 'medicinal product' see PARA 7 ante. As to

the description of medicinal products see PARA 7 note 33 ante. As to the meaning of 'business' see PARA 7 note 11 ante. As to references to retail sale and selling by retail see PARA 7 note 12 ante.

3 Any reference to the request or consent of a commercially interested party includes a reference to any request made or consent given by a person acting on behalf of a commercially interested party: *ibid* s 92(4).

4 For the meaning of 'advertisement', and as to references to 'the issue of an advertisement', see PARA 157 ante. Whether or not it contains an accurate statement of the composition of medicinal products of the description in question, an advertisement is to be taken to be false or misleading if, but only if: (1) it falsely describes the description of medicinal products to which it relates (*ibid* s 93(7)(a)); or (2) it is likely to mislead as to the nature or quality of medicinal products of that description or as to their uses or effects (s 93(7)(b)). Any reference to a false or misleading representation is to be construed in a corresponding way: s 93(7). For the meaning of 'composition' see PARA 44 note 14 ante. As to the meaning of 'likely to mislead' in relation to a document, advertisement or representation see PARA 152 note 18 ante. Particulars of an offence charged under s 93(7)(b) should specify the element or elements relied upon: *R v Roussel Laboratories Ltd, R v Good* (1988) 88 Cr App Rep 140, CA.

5 Medicines Act 1968 s 93(1). As to the penalties for such an offence see note 21 *infra*. As to defences to such an offence see PARA 160 post.

6 *Ie* a licence granted under *ibid* Pt II (as amended): see PARA 42 *et seq* ante.

7 'Unauthorised recommendations' in these circumstances means recommendations whereby medicinal products of a description to which the licence in question is applicable are recommended to be used for purposes other than those specified in the licence: *ibid* s 93(10).

8 *Ibid* s 93(2). As to the penalties for such an offence see note 21 *infra*. As to defences to such an offence see PARA 160 post.

9 'Relevant business' means any business which consists of or includes the sale or supply of medicinal products: *ibid* s 92(4).

10 For the meaning of 'representation' see PARA 158 note 14 ante. See also note 4 *supra*.

11 Medicines Act 1968 s 93(3). As to the penalties for such an offence see note 21 *infra*. As to defences to such an offence see PARA 160 post.

12 For the meaning of 'practitioner' see PARA 7 note 10 ante.

13 Medicines Act 1968 s 93(3)(a).

14 *Ibid* s 93(3)(b).

15 *Ibid* s 93(3)(c).

16 *Ibid* s 93(3). As to the penalties for such an offence see note 21 *infra*. As to defences to such an offence see PARA 160 post.

17 *Ibid* s 93(4)(a).

18 *Ie* the purposes specified in *ibid* s 93(3)(a)-(c): see the text to notes 12-15 *supra*.

19 *Ibid* s 93(4)(b).

20 *Ibid* s 93(4). As to the penalties for such an offence see note 21 *infra*. As to defences to such offences see PARA 160 post.

21 See *ibid* s 93(9) (amended by virtue of the Magistrates' Courts Act 1980 s 32(2)). Such a person is liable on summary conviction to a fine not exceeding the prescribed sum (Medicines Act 1968 s 93(9)(a) (as so amended)), or on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both (s 93(9)(b) (as so amended)). As to the prescribed sum see PARA 32 note 3 ante. As to enforcement, prosecution, general defences and related matters see PARA 176 *et seq* post.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(10) ADVERTISING/160. Defences to charges of false or misleading advertisements or representations.

160. Defences to charges of false or misleading advertisements or representations.

Where a person¹ is charged with an offence relating to false or misleading² advertisements³ or representations⁴ it is a defence for him to prove that he did not know and could not with reasonable diligence have discovered that the advertisement or representation was false or misleading⁵; and where he is charged with an offence relating to the issue of an advertisement⁶ or the making of a representation consisting of or including unauthorised recommendations⁷ it is a defence for him to prove that he did not know and could not with reasonable diligence have discovered that the recommendations made by the advertisement or representation were unauthorised recommendations⁸.

Where a person is charged with an offence⁹ in respect of the issue of an advertisement it is also a defence for him to prove that he is a person whose business¹⁰ it is to issue or arrange for the issue of advertisements¹¹ and that:

- 138 (1) he received the advertisement for issue in the ordinary course of business and issued it, or arranged for it to be issued, either unaltered or without any alteration except in respect of lettering or layout¹²; or
- 139 (2) not being a commercially interested party¹³, he received from such a party the information on which the advertisement was based and in the ordinary course of business prepared the advertisement in accordance with that information for issue at the request of that party¹⁴,

and, in either case, that he did not know and had no reason to suspect that the issue of the advertisement would amount to an offence¹⁵.

In certain circumstances it may also be a defence for a person charged with an offence¹⁶ to prove that the contravention was due to the default of some other person¹⁷.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 As to false and misleading advertisements and representations see PARA 159 note 4 ante.

3 Is an offence under the Medicines Act 1968 s 93(1): see PARA 159 ante. For the meaning of 'advertisement' see PARA 157 ante.

4 Is an offence under ibid s 93(3): see PARA 159 ante. For the meaning of 'representation' see PARA 158 note 14 ante.

5 Ibid s 93(5)(a). As to the standard of proof on the accused see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(3) (2006 Reissue) PARA 1372.

6 As to references to 'the issue of an advertisement' see PARA 157 ante.

7 Is an offence under the Medicines Act 1968 s 93(2) or s 93(4): see PARA 159 ante. For the meaning of 'unauthorised recommendations' see PARA 159 note 7 ante.

8 Ibid s 93(5)(b).

9 Is an offence under ibid s 93: see PARA 159 ante.

10 As to the meaning of 'business' see PARA 7 note 11 ante.

- 11 Medicines Act 1968 s 93(6).
- 12 Ibid s 93(6)(a).
- 13 For the meaning of 'commercially interested party' see PARA 159 note 2 ante.
- 14 Medicines Act 1968 s 93(6)(b). As to references to the request of a commercially interested party see PARA 159 note 3 ante.
- 15 Ibid s 93(6).
- 16 Ie under ibid s 93 (as amended): see PARA 159 ante.
- 17 Ie the provisions of ibid s 93(1)-(7) have effect subject to s 121 (see PARA 179 post): see s 93(8).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(10) ADVERTISING/161. Advertisements relating to medicinal products for which there is a product licence.

161. Advertisements relating to medicinal products for which there is a product licence.

Where a product licence¹ is in force which is applicable to medicinal products of a particular description², no commercially interested party³, other than the holder⁴ of the licence, and no other person⁵ at the request or with the consent of a commercially interested party⁶, may issue or cause another person to issue any advertisement⁷ relating to medicinal products of that description except with the consent of the holder of the licence⁸. Any person who contravenes⁹ these provisions is guilty of an offence¹⁰.

Where a product licence which is a licence of right¹¹ is in force in respect of a medicinal product, no advertisement relating to that product, other than a reference advertisement¹² or trade advertisement¹³, may be issued by a commercially interested party or by any person at the request or with the consent of a commercially interested party unless one or more of the following conditions are fulfilled¹⁴: (1) that the relevant product licence contains certain provisions relating to advertisements¹⁵; or (2) that the licensing authority¹⁶ has consented in writing¹⁷ to the issue of the advertisement or, having been notified in writing that it is intended to issue it, has not specified, within 42 days from being notified, that the advertisement should not¹⁸ be issued¹⁹. Any person who contravenes this provision is guilty of an offence²⁰.

1 For the meaning of 'product licence' see PARA 44 note 5 ante.

2 For the meaning of 'medicinal product' see PARA 7 ante. As to the description of medicinal products see PARA 7 note 33 ante.

3 For the meaning of 'commercially interested party' see PARA 159 note 2 ante.

4 As to references to the holder of a licence see PARA 66 note 5 ante.

5 For the meaning of 'person' see PARA 21 note 7 ante.

6 As to the request or consent of a commercially interested party see PARA 159 note 3 ante.

7 For the meaning of 'advertisement', and as to references to 'the issue of an advertisement', see PARA 157 ante.

8 Medicines Act 1968 s 94(1).

9 For the meaning of 'contravene' see PARA 6 note 21 ante.

10 Medicines Act 1968 s 94(2) (amended by virtue of the Criminal Justice Act 1982 ss 37, 38, 46). Such a person is liable on summary conviction to a fine not exceeding level 3 on the standard scale: see the Medicines Act 1968 s 94(2) (as so amended). As to the standard scale see PARA 6 note 22 ante. In certain circumstances, a defence under s 121 (see PARA 179 post) is available where the person charged proves that his contravention was due to the default of another person: s 94(2). As to enforcement, prosecution, other defences and related matters see PARA 176 et seq post.

11 As to licences of right see PARA 12 note 23 ante.

12 'Reference advertisement' means an advertisement which is in the form of and limited to a brief description of a medicinal product, its uses and any contra-indications and warnings relating to it appearing without charge in a publication consisting wholly or mainly of such advertisements where the publication is sent or delivered to practitioners or pharmacists by a person who is not a commercially interested party: Medicines (Advertising of Medicinal Products) Regulations 1975, SI 1975/298, reg 1(2). For the meaning of 'practitioner' see PARA 7 note 10 ante. For the meaning of 'pharmacist' see PARA 46 note 10 ante.

13 'Trade advertisement' means an advertisement relating to a medicinal product issued by means of a catalogue, price list or other document for the purpose of the sale (whether by the person who manufactures it or otherwise) of that medicinal product to persons who buy the product for the purpose of selling or supplying it, or administering it or causing it to be administered to one or more human beings, in the course of a business carried on by that person, where that catalogue, price list or document does not contain any recommendation relating to the use of the medicinal product other than as part of the name of the medicinal product or as part of any heading or sub-heading indicating a therapeutic classification: *ibid* reg 1(2). As to the meanings of 'manufacture' and 'administer' see *PARA 7* note 2 *ante*. As to the meaning of 'business' see *PARA 7* note 11 *ante*.

14 *Ibid* reg 2(1).

15 *Ibid* reg 2(2)(i), (ii). The licence must either be deemed by virtue of the Medicines Act 1968 s 47(4), (5) (see *PARA 67* *ante*) to have incorporated the standard provisions contained in the Medicines (Standard Provisions for Licences and Certificates) Regulations 1971, SI 1971/972, Sch 1 Pt I paras 9-11 (added by SI 1974/1523), or must have been varied under the Medicines Act 1968 s 30 (see *PARA 78* *ante*) so as to include identical or equivalent provisions: Medicines (Advertising of Medicinal Products) Regulations 1975, SI 1975/298, reg 2(i), (ii). For deemed compliance with this provision in respect of certain medicinal products covered by the Medicines (Exemption from Licences) (Food and Cosmetics) Order 1971, SI 1971/1410 (amended by SI 1973/2079) see the Medicines (Advertising of Medicinal Products) Regulations 1975, SI 1975/298, reg 2(3).

16 For the meaning of 'the licensing authority' see *PARA 43* note 8 *ante*.

17 For the meaning of 'writing' see *PARA 21* note 6 *ante*.

18 *Ie* for any of the purposes referred to in the Medicines Act 1968 s 95(4): see *PARA 158* *ante*.

19 Medicines (Advertising of Medicinal Products) Regulations 1975, SI 1975/298, reg 2(2)(iii).

20 *Ibid* reg 4. Such a person is liable on summary conviction to a fine not exceeding the statutory maximum (reg 4(a) (amended by virtue of the Criminal Justice Act 1988 s 51)), or on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both (Medicines (Advertising of Medicinal Products) Regulations 1975, SI 1975/298, reg 4(b)). As to the statutory maximum see *PARA 32* note 3 *ante*.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(10) ADVERTISING/162. Advertisements directed to the public.

162. Advertisements directed to the public.

Subject to specified exceptions¹, no advertisement² may be issued which is likely to lead to the use, except under the instruction of a doctor or dentist³, of any medicinal product or other substance⁴ or article for the treatment⁵ of human beings for venereal disease⁶, tuberculosis, cancer, diabetes⁷, epilepsy or fits, kidney disease, PARALYSIS, cataract or glaucoma, or the diagnosis of any of these diseases⁸, or for the purpose of procuring the miscarriage of women⁹. Subject to the same exceptions, no advertisement may be issued relating to any medicinal product for administration to human beings, other than a prescription only medicine or a medicinal product specified in an order¹⁰ restricting its sale or supply which is likely to lead to its use for the treatment of other specified diseases, adverse conditions and physical injuries¹¹. A similar prohibition applies to the making of representations by commercially interested parties which are likely to lead to the use of any medicinal product or other substance or article for such treatment¹². Subject to the same exceptions, no advertisement may be issued which is likely to lead to the use for administration to human beings of any prescription only medicinal product or any medicinal product specified in an order restricting its sale or supply¹³.

No advertisement relating to a spermicidal contraceptive¹⁴ may contain any statement or suggestion that such a contraceptive is a highly reliable means of contraception when used or applied otherwise than in conjunction with another method of contraception¹⁵; and every such advertisement must, in a prominent position, contain a prescribed warning¹⁶.

No advertisement relating to any medicinal product for use by being administered to human beings may contain any reference to the Commission on Human Medicines¹⁷, an appropriate committee¹⁸ or the licensing authority, unless such reference is specifically required by the licensing authority¹⁹.

Any person who contravenes²⁰ these provisions is guilty of an offence²¹.

1 The Medicines (Labelling and Advertising to the Public) Regulations 1978, SI 1978/41 (as amended) provide general exceptions from the restrictions imposed in respect of any advertisement a copy of which has been sent by the product licence holder to the licensing authority and which that authority has not prohibited by notice within 42 days thereafter: see reg 8(1). For the meaning of 'advertisement', and as to references to 'the issue of an advertisement', see PARA 157 ante. For the meaning of 'product licence' see PARA 44 note 5 ante. As to references to the holder of a licence or certificate see PARA 66 note 5 ante. The exceptions are: in respect of replies to specific inquiries (reg 8(2)(a)); in respect of communications to members of either House of Parliament (reg 8(2)(b)); in respect of representations made by commercially interested parties, or any advertisement sent exclusively to, or included in a journal etc directed mainly to, specified persons professionally involved with medicinal products (reg 8(2)(c)); in respect of references to prescription only medicines in statutory reports of companies (reg 8(2)(d)); in respect of any material not prepared or issued by a commercially interested party the purpose of which is not to induce any person to purchase or to ask a doctor to prescribe any medicinal product (reg 8(2)(e)); in respect of any notice displayed for the purpose of encouraging employees to participate in a health care programme (reg 8(2)(f)); in respect of labels or leaflets supplied with medicinal products prepared for administration in accordance with a prescription (reg 9(1)); in specified circumstances, in respect of labels or leaflets supplied with herbal remedies or medicinal products at high dilution by a registered pharmacist (reg 9(2)-(4)); and in respect of advertisements corresponding with the terms of a product licence for certain classes of medicinal products (reg 10). For the meaning of 'commercially interested party' see PARA 159 note 2 ante. For the meaning of 'medicinal product' see PARA 7 ante. As to prescription only medicines see PARA 140 et seq ante. For the meaning of 'doctor' see PARA 7 note 10 ante. For the meaning of 'label' see PARA 152 note 4 ante; and as to the meaning of 'leaflet' see PARA 153 note 5 ante. For the meaning of 'herbal remedy' see PARA 7 note 14 ante. For the meaning of 'pharmacist' see PARA 46 note 10 ante.

The Medicines (Labelling and Advertising to the Public) Regulations 1978, SI 1978/41 (as amended) do not apply to any advertisement or representation relating to a relevant medicinal product where 'relevant medicinal product' means:

- 71 (1) a medicinal product for human use to which EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) on the Community code relating to medicinal products for human use (as amended) applies and accordingly includes products to which EC Parliament and Council Regulation 726/2004 (OJ L137, 30.4.2004, p 1) Title II applies; or
- 72 (2) a substance or article for human use to which EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) (as amended) applies, and specified in an order made under the Medicines Act 1968 ss 104, 105 (see PARA 9 ante) or in regulations made under the European Communities Act 1972 s 2(2), which direct that the Medicines Act 1968 Pt VI (ss 92-97) (as amended) or any provision of that Part is to have effect in relation to such substance or article as that Part or provision has effect in relation to medicinal products within the meaning of the Act,

but does not include a homoeopathic medicinal product in respect of which there is in force a product licence being a licence of right: Medicines (Labelling and Advertising to the Public) Regulations 1978, SI 1978/41, reg 1A (added by SI 1994/1932); Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 2(1) (definition amended by SI 1999/267; SI 2002/236; SI 2005/2787). For the meaning of 'representation' see PARA 158 note 14 ante. 'Homoeopathic medicinal product' means a medicinal product (which may contain a number of principles) prepared from substances called homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, any pharmacopoeia used officially in a member state: Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 2(1) (definition added by SI 2005/2787). As to licences of right see PARA 12 note 23 ante. As to the European Pharmacopoeia see PARA 148 note 24 ante. For the meaning of 'member state' see the Interpretation Act 1978 s 5, Sch 1; European Communities Act 1972 s 1(2), Sch 1 Pt II.

2 Note that the exclusion from the definition of 'advertisement' of leaflets and labels (see the Medicines Act 1968 s 92(3); and PARA 157 ante) does not apply to the Medicines (Labelling and Advertising to the Public) Regulations 1978, SI 1978/41 (as amended): see the Medicines Act 1968 s 95(7); and PARA 158 note 4 ante. For the purposes of the Medicines (Labelling and Advertising to the Public) Regulations 1978, SI 1978/41, regs 2, 4, the sale or supply or offer or exposure for sale or supply of a medicinal product in a labelled container or package or the supply with a medicinal product of a leaflet relating solely to medicinal products of that description must be included among the acts taken to constitute the issue of an advertisement: regs 2(3), 4(3). For the meanings of 'container' and 'package' see PARA 152 note 4 ante.

3 For the meaning of 'dentist' see PARA 7 note 10 ante.

4 For the meaning of 'substance' see PARA 7 note 1 ante.

5 For the meaning of 'treatment' see PARA 8 note 1 ante.

6 'Venereal disease' means syphilis, gonorrhoea or soft chancre: Medicines (Labelling and Advertising to the Public) Regulations 1978, SI 1978/41, reg 1(2).

7 This prohibition does not apply to the issue of an advertisement relating to a medicinal product or other substance or article sold or supplied as a food or dietary supplement for persons suffering from diabetes: *ibid* reg 2(2).

8 *Ibid* reg 2(1)(a), Sch 1.

9 *Ibid* reg 2(1)(b). As to offences relating to the procurement of miscarriages see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(1) (2006 Reissue) PARAS 109-111; MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 207.

10 *Ie* an order under the Medicines Act 1968 s 62(1): see PARA 48 ante.

11 Medicines (Labelling and Advertising to the Public) Regulations 1978, SI 1978/41, reg 4, Sch 2.

12 See *ibid* reg 5(1). In certain circumstances, representations made by pharmacists, chiropodists, registered nurses or registered midwives are exempted from this prohibition: see reg 5(2) (amended by SI 2002/880; SI 2003/1590; SI 2004/1771). 'Registered midwife' means a person registered in the Midwives' Part of the register maintained by the Nursing and Midwifery Council under the Nursing and Midwifery Order 2001, SI 2002/253, art 5; and 'registered nurse' means a person registered in the Nurses' Part of such register: Medicines (Labelling and Advertising to the Public) Regulations 1978, SI 1978/41, reg 1(2) (amended by SI 2004/1771). As to the regulation of the professions of pharmacists, chiropodists, nurses and midwives see MEDICAL PROFESSIONS.

13 See the Medicines (Labelling and Advertising to the Public) Regulations 1978, SI 1978/41, reg 3.

14 'Spermicidal contraceptive' means a contraceptive substance or article (not being a veterinary drug) which acts wholly or mainly by chemical spermicidal means, but does not include such a substance or article which is administered orally, an intra-uterine contraceptive device or a spermicidal lubricant which is or is to be applied to a condom, cap or diaphragm: *ibid* reg 1(2). For the meaning of 'veterinary drug' see *PARA 3* note 7 *ante*.

15 *Ibid* reg 6(1).

16 *Ibid* reg 6(2), Sch 3.

17 As to the constitution of the Commission see *PARA 13* *ante*.

18 For the meaning of 'the appropriate committee' see *PARA 15* note 5 *ante*.

19 Medicines (Labelling and Advertising to the Public) Regulations 1978, SI 1978/41, reg 7.

20 For the meaning of 'contravene' see *PARA 6* note 21 *ante*.

21 Medicines (Labelling and Advertising to the Public) Regulations 1978, SI 1978/41, reg 12. Such a person is liable on summary conviction to a fine not exceeding the statutory maximum (reg 12(a) (amended by virtue of the Criminal Justice Act 1988 s 51)), or on conviction on indictment to a fine or imprisonment for a term not exceeding two years or both (Medicines (Labelling and Advertising to the Public) Regulations 1978, SI 1978/41, reg 12(b)). As to the statutory maximum see *PARA 32* note 3 *ante*.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(10) ADVERTISING/163. Advertising to the public.

163. Advertising to the public.

No person¹ may issue an advertisement² relating to a relevant medicinal product:

- 140 (1) in respect of which no marketing authorisation³ or traditional herbal registration⁴ is in force⁵;
- 141 (2) unless that advertisement complies with the particulars listed in the summary of product characteristics⁶;
- 142 (3) unless that advertisement encourages the rational use of that product by presenting it objectively and without exaggerating its properties⁷;
- 143 (4) that is misleading⁸.

In relation to advertisements wholly or mainly directed at members of the general public⁹, no person may issue an advertisement:

- 144 (a) which is likely to lead to the use of a relevant medicinal product or any other medicinal product, substance or article for the purpose of inducing an abortion in women¹⁰;
- 145 (b) which is likely to lead to the use of a relevant medicinal product which is a medicinal product for supply by prescription only and which is subject to any of the specified restrictions¹¹;
- 146 (c) relating to any relevant medicinal product which contains certain narcotic or psychotropic substances¹²;
- 147 (d) relating to any relevant medicinal product which contains any of certain specified material¹³;
- 148 (e) relating to a relevant medicinal product unless that advertisement is set out in such a way that it is clear that the message is an advertisement and so that the product is clearly identified as a medicinal product¹⁴, and includes the specified information¹⁵.

No person being the holder of a marketing authorisation, traditional herbal registration or certificate of registration¹⁶, or in the course of a business¹⁷ carried on by him and consisting, wholly or partly, of manufacturing¹⁸ relevant medicinal products or of selling or supplying relevant medicinal products¹⁹, may for a promotional purpose, whether a promotional purpose of his own or of a third party, sell or supply any relevant medicinal product to any member of the public²⁰.

No person may issue an advertisement relating to a registered homoeopathic medicinal product which contains any details which are not specified details²¹ or mentions any specific therapeutic indications²²; and no person may issue an advertisement relating to a herbal medicinal product²³ which is marketed in the United Kingdom under a traditional herbal registration which does not contain a statement in the specified form²⁴.

Any person who contravenes²⁵ these provisions is guilty of an offence²⁶.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 'Advertisement' has the meaning assigned to it by the Medicines Act 1968 s 92 (as amended) (see PARA 157 ante), except that, in relation to a relevant medicinal product, provided that it makes no product claim,

reference material, a factual, informative statement or announcement, a trade catalogue or a price list must not be taken to be an advertisement; and an advertisement includes a representation: Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 2(2). For this purpose, 'representation' has the meaning assigned to it by the Medicines Act 1968 s 92 (as amended) (see PARA 158 note 14 ante), except that it does not include the making of a factual, informative statement or announcement which includes no product claim: Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 2(2). For the meaning of 'relevant medicinal product' see PARA 162 note 1 ante. 'Reference material' includes entries which are in the form of, and limited to, a brief description of a medicinal product, its uses and any relevant contra-indications and warnings, appearing without charge in a publication consisting wholly or mainly of such entries where the publication is sent or delivered to persons qualified to prescribe or supply relevant medicinal products by a person who is not a commercially interested party: reg 2(1). For the meaning of 'commercially interested party' see PARA 159 note 2 ante.

3 'Marketing authorisation' means: (1) a marketing authorisation granted by the licensing authority under the Medicines for Human Use (Marketing Authorisations Etc) Regulations 1994, SI 1994/3144 (as amended) (see PARA 20 ante); (2) a marketing authorisation granted by the European Commission under EC Council Regulation 2309/93 (OJ L214, 24.8.1993, p 1) (see PARA 19 ante) or under EC Parliament and Council Regulation 726/2004 (OJ L37, 30.4.2004, p 1) laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency; (3) an authorisation granted by the licensing authority in accordance with EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 126a; or (4) a product licence granted by the licensing authority under the Medicines Act 1968 Pt II (ss 6-50): Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 2(1) (definition substituted by SI 2005/2787). For the meaning of 'the licensing authority' see PARA 43 note 8 ante. For the meaning of 'product licence' see PARA 44 note 5 ante.

4 'Traditional herbal registration' means a registration granted by the licensing authority under the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, SI 2005/2750 (see PARA 230 post): Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 2(1) (definition added by SI 2005/2787).

5 Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 3(1) (amended by SI 1994/3144; SI 2005/2787). This provision does not apply to any advertisement relating to a registered homoeopathic medicinal product: Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 3(2). 'Registered homoeopathic medicinal product' means a homoeopathic medicinal product to which EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) (amended by EC Parliament and Council Directive 2002/98 (OJ L033, 8.2.2003, p 30), EC Commission Directive 2003/63 (OJ L159, 27.6.2003, p 46), EC Parliament and Council Directive 2004/24 (OJ L136, 30.4.2004, p 85) and EC Parliament and Council Directive 2004/27 (OJ L136, 30.4.2004, p 34)) applies which is marketed in the United Kingdom under a certificate of registration in accordance with the provisions of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105 (as amended): Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 2(1) (definition amended by SI 2002/236; SI 2005/2787). For the meaning of 'homoeopathic medicinal product' see PARA 162 note 1 ante. For the meaning of 'United Kingdom' see PARA 7 note 3 ante. 'Certificate of registration' means a certificate of registration granted by the licensing authority under the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105 (see PARA 205 post): Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 2(1) (definition added by SI 2005/2787).

6 Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 3A(1) (reg 3A added by SI 1999/267). 'Summary of product characteristics' means the information required to accompany any application for a marketing authorisation or traditional herbal registration by virtue of EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 11: Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 2(1) (definition amended by SI 2002/236; SI 2005/2787).

7 Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 3A(2) (as added: see note 6 supra).

8 Ibid reg 3A(3) (as added: see note 6 supra). As to the monitoring of advertisements governed by the Medicines (Advertising) Regulations 1994, SI 1994/1932 (as amended) see PARA 167 post.

9 Ibid reg 5.

10 Ibid reg 6(3). For the meaning of 'substance' see PARA 7 note 1 ante. As to the law relating to abortions see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(1) (2006 Reissue) PARA 109 et seq; MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 209.

11 Ibid reg 7. The specified restrictions are those imposed by the Medicines Act 1968 s 58(2) (see PARA 140 ante). 'Medicinal product for supply by prescription only' means a medicinal product of a description or falling within a class specified in any order made under s 58 (as amended) (see PARA 140 ante): Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 2(1). The provisions of regs 7, 8 and 9(1)(d) do not apply to any advertisement as part of a vaccination campaign relating to a relevant medicinal product which is a vaccine or serum, provided that such campaign has been approved by the health ministers: reg 11 (amended by SI 2005/2787). The functions of the health ministers under the regulations may be performed by any one of them

acting alone or any two or more of them acting jointly: Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 2(4) (added by SI 1999/267). For the meaning of 'the health ministers' see PARA 3 note 4 ante.

12 See the Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 8. See also note 11 supra.

13 Ibid reg 9(1). See also note 11 supra. The specified material is any which: (1) gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by post, fax or telephone (reg 9(1)(a)); (2) suggests that the effects of taking the medicinal product are guaranteed, are unaccompanied by side effects or are better than, or equivalent to, those of another identifiable treatment or medicinal product (reg 9(1)(b)); (3) suggests that health can be enhanced by taking the medicinal product (reg 9(1)(c)); (4) suggests that health could be affected by not taking the medicinal product (reg 9(1)(d)); (5) is directed exclusively or principally at children (reg 9(1)(e)); (6) refers to a recommendation by scientists, health professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of medicinal products (reg 9(1)(f)); (7) suggests that the medicinal product is a foodstuff, cosmetic or other consumer product (reg 9(1)(g)); (8) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural (reg 9(1)(h)); (9) might, by a description or detailed representation of a case history, lead to erroneous self-diagnosis (reg 9(1)(i)); (10) refers, in improper, alarming or misleading terms, to claims of recovery (reg 9(1)(j)); (11) uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof (reg 9(1)(k)). 'Fax' means the making of a facsimile copy of a document by the transmission of electronic signals: reg 9(2).

14 Ibid reg 10(1)(a). Regulation 10 does not apply to an advertisement relating to a relevant medicinal product which is on a promotional aid if the advertisement consists solely of the name of the product or its international non-proprietary name, where this exists, or the trademark (or, in the case of a registered homoeopathic medicinal product, the scientific name of the stock or stocks or its invented name) (reg 10(2)(a) (substituted by SI 2005/2787)), and the advertisement is intended solely as a reminder (Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 10(2)(b)). 'Promotional aid' means a non-monetary gift made for a promotional purpose by a commercially interested party: reg 2(1).

15 Ibid reg 10(1)(b). The specified information is: the name of the medicinal product; if it contains only one active ingredient, the common name of the medicinal product; the information necessary for correct use of the medicinal product; and an express and legible invitation to read carefully the instructions on the leaflet contained within the package or on the label, as the case may be: reg 10(1)(b)(i)-(iv). 'Name' in relation to a relevant medicinal product means the name given to the product which may be either an invented name or a common or scientific name, together with a trade mark or the name of the person responsible for marketing the product; and 'common name' in relation to a relevant medicinal product means the international non-proprietary name, or, if one does not exist, the usual common name: reg 2(1). As to the meaning of 'leaflet' see PARA 153 note 5 ante. For the meaning of 'label' see PARA 152 note 4 ante.

16 Ibid reg 12(a) (reg 12 substituted by SI 1999/267; and amended by SI 2005/2787). As to the duties of licence holders in relation to the collation of information relating to products, the training of sales representatives and the provision of sample advertisements and information to the health ministers see the Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 4 (amended by SI 2005/2787).

17 As to the meaning of 'business' see PARA 7 note 11 ante.

18 As to the meaning of 'manufacture' see PARA 7 note 2 ante.

19 Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 12(b).

20 Ibid reg 12.

21 Ibid reg 22(1)(a). For the specified details see Sch 5 (amended by SI 2005/2787). Nothing in the Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 10(1)(b) (see the text to note 15 supra) is to be construed as requiring the inclusion of any detail which is not specified in Sch 5 (as amended) in an advertisement relating to a registered homoeopathic medicinal product: reg 22(2).

22 Ibid reg 22(1)(b).

23 For these purposes, 'herbal medicinal product' has the meaning given by EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 1(30): Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 22A(3) (reg 22A added by SI 2005/2787).

24 Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 22A(1) (as added: see note 23 supra). As to the specified form see reg 22A(2) (as so added).

25 For the meaning of 'contravene' see PARA 6 note 21 ante.

26 Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 23(1) (amended by SI 2005/2787). Such a person is liable on summary conviction to a fine not exceeding the statutory maximum (reg 23(1)(a) (amended by SI 1999/267)), or on conviction on indictment to a fine or imprisonment for a term not exceeding two years or both (Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 23(1)(b)). As to the statutory maximum see PARA 32 note 3 ante. The Medicines Act 1968 ss 107-108 (see PARAS 79 ante, 168 post), ss 111-116 (see PARAS 169-173 post), ss 118, 119 (see PARAS 174-175 post), ss 121-126 (see PARAS 179-181, 183-184 post), s 127 (see PARA 37 note 8 ante) and Sch 3 (see PARA 171 post) apply for the purposes of the Medicines (Advertising) Regulations 1994, SI 1994/1932 (as amended) as they apply for the purposes of the Act: reg 23(3) (added by SI 1999/267).

UPDATE

163 Advertising to the public

NOTE 5--Directive 2001/83 further amended: European Parliament and EC Council Regulations 1901/2006 (OJ L378, 27.12.2006, p 1), 1394/2007 (OJ L324, 10.12.2007, p 121) and European Parliament and EC Council Directive 2008/29 (OJ L81, 20.3.2008, p 51).

NOTES 7, 20--See Case C-374/05 *Gintec International Import-Export GMBH v Verband Sozialer Wettbewerb EV* [2008] 1 CMLR 808, ECJ (advertising of relevant medicinal product by means of prize draw was precluded, as it encouraged irrational use and amounted to direct distribution to the general public).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(10) ADVERTISING/164. Advertisements and representations directed to practitioners.

164. Advertisements and representations directed to practitioners.

No advertisement¹ relating to medicinal products of a particular description², other than a data sheet³, may be sent or delivered to a practitioner⁴ by a commercially interested party⁵, or by any person at the request or with the consent of a commercially interested party⁶, and no representation⁷ likely to promote the use of medicinal products of a particular description referred to in the representation may be made to a practitioner by a person carrying on a relevant business⁸, or by a person acting on behalf of a person carrying on such a business⁹, unless the following conditions are fulfilled¹⁰: (1) that a data sheet relating to medicinal products of the description in question is sent or delivered to the practitioner with the advertisement, or is delivered to him at the time when the representation is made, or that such a data sheet has been sent or delivered to him not more than 15 months before the date on which the advertisement is sent or delivered or the representation is made¹¹; and (2) that the advertisement or representation is not inconsistent with the particulars contained in the data sheet¹². Any person who contravenes¹³ these provisions is guilty of an offence¹⁴.

Subject to certain exceptions¹⁵, every advertisement (other than a data sheet, reference advertisement¹⁶ or trade advertisement¹⁷) relating to a medicinal product¹⁸ other than a veterinary drug¹⁹, issued in a professional publication²⁰ by a commercially interested party or by any person at the request or with the consent of such a party must state that a relevant data sheet will, on written²¹ request, be sent or delivered to any relevant practitioner²². In so far as the advertisement contains particulars in respect of information contained in a relevant data sheet, these particulars must not be inconsistent with that data sheet²³. A product licence holder will not be regarded as complying with these requirements if he fails to comply with such a request from a practitioner or if he has not sent three copies of a relevant data sheet to the licensing authority²⁴ not more than 15 months before the issue of the advertisement²⁵. Any person who contravenes these provisions is guilty of an offence²⁶.

1 For the meaning of 'advertisement', and as to references to 'the issue of an advertisement', see PARA 157 ante.

2 Nothing in the Medicines Act 1968 s 96 (as amended) applies in relation to a relevant medicinal product, as defined by the Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 2(1) (see PARA 162 note 1 ante) in respect of which there is required to exist a summary of product characteristics (see PARA 163 note 5 ante): Medicines Act 1968 s 96(7) (added by the Medicines Act 1968 (Amendment) Regulations 1995, SI 1995/2321, reg 2). For the meaning of 'medicinal product' see PARA 7 ante. As to the description of medicinal products see PARA 7 note 33 ante.

3 'Data sheet' means a document relating to medicinal products of a particular description which is prepared by or on behalf of the holder of a product licence which is applicable to medicinal products of that description and which: (1) complies with such requirements as to dimensions and form, as to the particulars to be contained in it, and as to the manner (whether in respect of type, size, colour or disposition of lettering or otherwise) in which any such particulars are to be so contained, as may be prescribed for the purpose (Medicines Act 1968 s 96(6)(a)); and (2) does not contain any information relating to medicinal products of that description except the particulars so prescribed (s 96(6)(b)). For the meaning of 'product licence' see PARA 44 note 5 ante; and as to references to the holder of a licence see PARA 66 note 5 ante. For the meaning of 'prescribed' see PARA 56 note 3 ante. As to the making of regulations see PARA 5 ante. As to the regulations that have been made see the Medicines (Data Sheet) Regulations 1972, SI 1972/2076 (amended by SI 1979/1760; SI 1981/1633; SI 1989/1183; SI 1994/3142; SI 1996/2420; SI 2000/2386; SI 2005/2787); the Medicines (Contact Lens Fluids and Other Substances) (Advertising and Miscellaneous Amendments) Regulations 1979, SI 1979/1760 (amended by SI 2005/848); and the Medicines (Data Sheet for Veterinary Drugs) Regulations 2000, SI 2000/2386.

4 For the meaning of 'practitioner' see PARA 7 note 10 ante.

5 Medicines Act 1968 s 96(1)(a). For the meaning of 'commercially interested party' see PARA 159 note 2 ante.

6 Ibid s 96(1)(b). As to references to the request or consent of a commercially interested party see PARA 159 note 3 ante. For the meaning of 'person' see PARA 21 note 7 ante.

7 For the meaning of 'representation' see PARA 158 note 14 ante.

8 For the meaning of 'relevant business' see PARA 159 note 9 ante.

9 Medicines Act 1968 s 96(2).

10 Ibid s 96(1), (2). These restrictions are expressed to have effect 'on and after the relevant date', which is defined, in relation to medicinal products to which the transitional provisions of s 16(2) or s 16(3) do not apply, as the first appointed day (ie 1 September 1971: see the Medicines (First Appointed Day) Order 1971, SI 1971/1153) and, in relation to medicinal products to which those provisions do apply, as the date of expiry of the period of six months from the date on which those provisions cease to have effect by virtue of an order under the Medicines Act 1968 s 17 (termination of transitional exemptions): see s 96(4); and the Medicines (Termination of Transitional Exemptions (No 1) Order 1972, SI 1972/1198; the Medicines (Termination of Transitional Exemptions (No 2) Order 1974, SI 1974/1149; the Medicines (Termination of Transitional Exemptions (No 3) Order 1975, SI 1975/761; the Medicines (Intra-Uterine Contraceptive Devices) (Termination of Transitional Exemptions) Order 1980, SI 1980/1467; and the Medicines (Contact Lens Fluids and Other Substances) (Termination of Transitional Exemptions) Order 1981, SI 1981/1690.

11 Medicines Act 1968 s 96(3)(a).

12 Ibid s 96(3)(b).

13 For the meaning of 'contravene' see PARA 6 note 21 ante.

14 Medicines Act 1968 s 96(5). If he contravenes the provisions as to consistency of the advertisement or representation with the data sheet (ie by not complying with the condition in head (2) in the text), he is liable on summary conviction to a fine not exceeding the prescribed sum, or on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both (Medicines Act 1968 s 96(5) (amended by virtue of the Magistrates' Courts Act 1980 s 32(2)); and, in any other case, he is liable on summary conviction to a fine not exceeding level 3 on the standard scale (Medicines Act 1968 s 96(5) (amended by virtue of the Criminal Justice Act 1982 ss 37, 46)). As to the standard scale see PARA 6 note 22 ante. As to the prescribed sum see PARA 32 note 3 ante. As to enforcement, prosecution, defences and related matters see PARA 176 et seq post. In certain circumstances a defence is available under the Medicines Act 1968 s 121 (see PARA 179 post) where the person charged proves that his contravention was due to the default of another person: see s 96(5).

15 See the Medicines (Advertising of Medicinal Products) (No 2) Regulations 1975, SI 1975/1326, reg 2(3).

16 'Reference advertisement' means an advertisement which is in the form of and limited to a brief description of a medicinal product, its uses and any contra-indications and warnings relating to it appearing without charge in a publication consisting wholly or mainly of such advertisements where the publication is sent or delivered to practitioners or pharmacists by a person who is not a commercially interested party: *ibid* reg 1(2). For the meaning of 'pharmacist' see PARA 46 note 10 ante.

17 'Trade advertisement' means an advertisement relating to a medicinal product issued by means of a catalogue, price list or other document for the purpose of the sale (whether by the person who manufactures it or otherwise) of that medicinal product to persons who buy the product for the purpose of selling or supplying it, or administering it or causing it to be administered to one or more human beings, in the course of a business carried on by that person, where that catalogue, price list or document does not contain any recommendation relating to the use of the medicinal product other than as part of the name of the medicinal product or as part of any heading or sub-heading indicating a therapeutic classification: *ibid* reg 1(2). As to the meanings of 'manufacture' and 'administer' see PARA 7 note 2 ante. As to the meaning of 'business' see PARA 7 note 11 ante.

18 'Medicinal product' includes any substance or article, except for the substances and fluids described in the Medicines (Specified Articles and Substances) Order 1976, SI 1976/968, Sch 1 para 2, which is specified in the Medicines (Surgical Materials) Order 1971, SI 1971/1267, in the Medicines (Dental Filling Substances) Order 1975, SI 1975/533, or in any other order made under the Medicines Act 1968 ss 104, 105 (see PARA 9 ante) subsequent to the coming into force of the Medicines (Advertising of Medicinal Products) (No 2) Regulations 1975, SI 1975/1326 (as amended) by virtue of which the Medicines Act 1968 s 96 (see note 10 *supra*) has effect in relation to such substance or article as it has effect in relation to medicinal products within the meaning of

the Act: Medicines (Advertising of Medicinal Products) (No 2) Regulations 1975, SI 1975/1326, reg 1(2) (definition amended by SI 1979/1760).

19 For the meaning of 'veterinary drug' see PARA 3 note 7 ante.

20 'Professional publication' means a publication sent or delivered wholly or mainly to doctors or dentists, a publication containing an advertisement relating to a medicinal product which may only lawfully be sold by retail or supplied in circumstances corresponding to retail sale in accordance with a prescription given by a practitioner, or a publication containing an advertisement relating to a medicinal product in respect of which a data sheet has been issued: Medicines (Advertising of Medicinal Products) (No 2) Regulations 1975, SI 1975/1326, reg 1(2). For the meanings of 'doctor' and 'dentist' see PARA 7 note 10 ante. As to references to retail sale and selling by retail see PARA 7 note 12 ante. As to references to supplying anything in circumstances corresponding to retail sale see PARA 7 note 13 ante.

21 For the meaning of 'written' see PARA 21 note 4 ante.

22 Medicines (Advertising of Medicinal Products) (No 2) Regulations 1975, SI 1975/1326, reg 2(1)(b). 'Relevant practitioner' means a doctor where the medicinal product is for use exclusively by or under the direction of a doctor, or a dentist where the medicinal product is for use exclusively by or under the direction of a dentist, or a doctor or dentist where the medicinal product is not for either such exclusive use: reg 1(2).

23 Ibid reg 2(1)(a).

24 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

25 Medicines (Advertising of Medicinal Products) (No 2) Regulations 1975, SI 1975/1326, reg 2(4).

26 Ibid reg 4. Such a person is liable on summary conviction to a fine not exceeding the statutory maximum (reg 4(a) (amended by virtue of the Criminal Justice Act 1988 s 51)), or on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both (Medicines (Advertising of Medicinal Products) (No 2) Regulations 1975, SI 1975/1326, reg 4(b)). As to the statutory maximum see PARA 32 note 3 ante.

UPDATE

164 Advertisements and representations directed to practitioners

NOTE 3--SI 1979/1760 further amended: SI 2007/3101. SI 2000/2386 revoked: SI 2005/2745.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(10) ADVERTISING/165. Advertising to health professionals.

165. Advertising to health professionals.

No person¹ may issue an advertisement wholly or mainly directed at persons qualified to prescribe or supply relevant medicinal products² which relates to a relevant medicinal product unless such advertisement contains essential information compatible with the summary of product characteristics³, contains the specified particulars⁴, and is in accordance with the specified requirements⁵. No person may issue in a programme service⁶ or video recording any advertisement relating to a relevant medicinal product which includes or shows any words, unless that advertisement contains essential information compatible with the summary of product characteristics⁷, and refers to the specified particulars⁸. No person may issue an abbreviated advertisement⁹ relating to a relevant medicinal product unless such advertisement contains essential information compatible with the summary of product characteristics¹⁰, contains the specified particulars¹¹, and any warning which the licensing authority¹² has required to be included in any advertisement relating to that medicinal product has been included¹³. However, none of these prohibitions and requirements apply to an advertisement relating to a relevant medicinal product which is on a promotional aid¹⁴ if the advertisement consists solely of the name¹⁵ of the product or its international non-proprietary name or trademark¹⁶ and the advertisement is intended solely as a reminder¹⁷.

No person may send or deliver to persons qualified to prescribe or supply relevant medicinal products as part of the promotion of a relevant medicinal product any written material¹⁸ relating to that product unless it includes essential information compatible with the summary of product characteristics¹⁹, contains the specified particulars²⁰, and states the date on which it was drawn up or last revised²¹. Where medical sales representatives promote relevant medicinal products to persons qualified to prescribe or supply such products they must comply with specified requirements²². Where relevant medicinal products are being promoted to persons qualified to prescribe or supply relevant medicinal products, no person may supply, offer or promise to such persons any gift, pecuniary advantage or benefit in kind, unless it is inexpensive and relevant to the practice of medicine or pharmacy²³. No person may offer hospitality, including the payment of travelling or accommodation expenses, at a meeting or event held for the promotion of relevant medicinal products unless such hospitality is strictly limited to the main purpose of the meeting or event²⁴, and the person to whom it is offered is a health professional²⁵.

Any person who contravenes²⁶ these provisions is guilty of an offence²⁷.

A person may only supply a free sample of a relevant medicinal product to a person who receives it for the purpose of acquiring experience in dealing with such a product²⁸ if certain conditions are satisfied²⁹. No person qualified to prescribe or supply relevant medicinal products may solicit or accept any prohibited³⁰ gift, pecuniary advantage, benefit in kind, hospitality or sponsorship³¹. Any person who contravenes either of these provisions is guilty of an offence³².

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 The Medicines (Advertising) Regulations 1994, SI 1994/1932, regs 14-18 (see the text and notes 3-21 infra) apply only to advertisements wholly or mainly directed at persons qualified to prescribe or supply relevant medicinal products; but nothing in regs 13-21 (as amended) has any effect in relation to veterinary surgeons or veterinary practitioners: reg 13(1), (2). For the meaning of 'advertisement' see PARA 163 note 2 ante. For the meaning of 'relevant medicinal product' see PARA 162 note 1 ante. For the meanings of 'veterinary surgeon' and 'veterinary practitioner' see PARA 7 note 10 ante. 'Persons qualified to prescribe or supply' includes persons, and

employees of such persons, who in the course of their profession or in the course of a business may lawfully prescribe, sell by retail or supply in circumstances corresponding to retail sale relevant medicinal products: reg 2(1). As to the meaning of 'business' see PARA 7 note 11 ante. As to references to retail sale and selling by retail see PARA 7 note 12 ante. As to references to supplying anything in circumstances corresponding to retail sale see PARA 7 note 13 ante.

3 Ibid reg 14(1)(a). 'Essential information compatible with the summary of product characteristics' means essential information compatible with the summary of product characteristics, if there is one, or if there is no summary of product characteristics, with the data sheet; and 'essential information' has the meaning it bears in EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) Title VIII: Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 2(1). For the meaning of 'summary of product characteristics' see PARA 163 note 6 ante. For the meaning of 'data sheet' see PARA 164 note 3 ante.

4 Ibid reg 14(1)(b). As to the specified particulars see Sch 2 paras 1-9 (paras 1, 2, 5 amended by SI 2005/2787).

5 Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 14(1)(c). As to the specified requirements see Sch 2 para 10. Regulation 14(1) does not apply to an advertisement to which regs 15, 16 apply (see the text to notes 6-13 infra): reg 14(2). As to the monitoring of advertisements governed by the Medicines (Advertising) Regulations 1994, SI 1994/1932 (as amended) see PARA 167 post.

6 'Programme service' has the meaning assigned to it in the Broadcasting Act 1990 s 201 (see TELECOMMUNICATIONS AND BROADCASTING vol 45(1) (2005 Reissue) PARA 328): Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 15(3).

7 Ibid reg 15(1)(a).

8 Ibid reg 15(1)(b). As to the specified particulars see Sch 2 paras 1-8. For these purposes, the particulars contained in Sch 2 may (where appropriate) be supplied by way of written material made available to all persons to whom the advertisement is shown or sent as an alternative to being referred to in the advertisement: reg 15(2). For the meaning of 'written' see PARA 21 note 4 ante.

9 'Abbreviated advertisement' means an advertisement, other than a loose insert, which does not exceed in size an area of 420 square centimetres, in a publication sent or delivered wholly or mainly to persons qualified to prescribe or supply relevant medicinal products: ibid reg 2(1).

10 Ibid reg 16(a).

11 Ibid reg 16(b). As to the specified particulars see Sch 3 (amended by SI 2005/2787).

12 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

13 Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 16.

14 For the meaning of 'promotional aid' see PARA 163 note 14 ante.

15 Or, in the case of a registered homoeopathic medicinal product, the scientific name of the stock or stocks or its invented name: Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 17(a) (amended by SI 2005/2787). For the meaning of 'name' see PARA 163 note 15 ante. For the meaning of 'registered homoeopathic medicinal product' see PARA 163 note 5 ante.

16 Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 17(a) (as amended: see note 15 supra).

17 Ibid reg 17(b).

18 No person may include any information in such written material which is not accurate, up-to-date, verifiable or sufficiently complete to enable the recipient to form his own opinion of the therapeutic value of the product to which the documentation relates (ibid reg 18(2)); and no person may include in such written material any quotation, table or other illustrative matter taken from a medical journal or other scientific work unless it is accurately reproduced and the precise sources of the information indicated (reg 18(3)).

19 Ibid reg 18(1)(a).

20 Ibid reg 18(1)(b). As to the specified particulars see specified in Sch 2 para 3.

21 Ibid reg 18(1)(c).

22 See *ibid* reg 20(1) (amended by SI 1999/267). In relation to any relevant medicinal product which they promote, all medical sales representatives must, during each visit, give to all persons whom they visit or have available for them a copy of the summary of product characteristics (or, if there is no summary of product characteristics, a copy of the data sheet) for each such product (Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 20(2)); and they must forthwith report all information which they receive from persons whom they visit, including reports of any adverse reactions, to the scientific service established by the person who holds a marketing authorisation relating to a relevant medicinal product in question (reg 20(3)). For the meaning of 'marketing authorisation' see PARA 163 note 3 *ante*. As to the obligation on holders of marketing authorisations to establish scientific services see reg 4; and PARA 163 note 16 *ante*.

23 *Ibid* reg 21(1). This provision does not prevent any person offering hospitality (including the payment of travelling or accommodation expenses) at events for purely professional or scientific purposes to persons qualified to prescribe or supply relevant medicinal products, provided that such hospitality is strictly limited to the main scientific objective of the event (reg 21(2)(a) (reg 21(2), (3) substituted by SI 2005/2787)), and it is offered only to health professionals (Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 21(2)(b) (as so substituted)). Measures or trade practices relating to prices, margins or discounts which were in existence on 1 January 1993 are not affected by these provisions: reg 21(4). As to the prohibition on the solicitation or acceptance of such gifts etc see the text to notes 30-31 *infra*.

24 *Ibid* reg 21(3)(a) (as substituted: see note 23 *supra*). See also the text to notes 30-31 *infra*.

25 *Ibid* reg 21(3)(b) (as substituted: see note 23 *supra*). See also the text to notes 30-31 *infra*. Regulation 21(3) (as substituted) does not affect measures or trade practices relating to prices, margins or discounts which were in existence on 1 January 1993: reg 21(4).

26 For the meaning of 'contravene' see PARA 6 note 21 *ante*.

27 Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 23(1). Such a person is liable on summary conviction to a fine not exceeding the statutory maximum (reg 23(1)(a)), or on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both (reg 23(1)(b)). As to the statutory maximum see PARA 32 note 3 *ante*. As to the application of certain provisions of the Medicines Act 1968 for the purposes of the Medicines (Advertising) Regulations 1994, SI 1994/1932 (as amended) see PARA 163 note 24 *ante*.

28 *Ibid* reg 19(1).

29 See *ibid* reg 19(2). The conditions are that the supply is to a person qualified to prescribe relevant medicinal products (reg 19(2)(a)); the sample is of a medicinal product which does not contain a substance which is listed in any of Schedules I, II or IV to the Single Convention on Narcotic Drugs signed by the United Kingdom on 30 March 1961 (New York 30 March to 1 August 1961; TS 34 (1965); Cmnd 2631) (where the product is not a preparation listed in Schedule III to that Convention) (Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 19(2)(b)(i)), or a substance which is listed in any of Schedules I to IV of the Convention on Psychotropic Substances (Vienna, 21 February 1971; TS 51 (1993); Cmnd 2307) (where the product is not a preparation which may be exempted from measures of control in accordance with art 3(2), (3)) (Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 19(2)(b)(ii)); and the supply must be in accordance with Sch 4 (reg 19(2)(c)).

30 Is prohibited by *ibid* reg 21: see the text to notes 23-25 *supra*.

31 *Ibid* reg 21(5).

32 *Ibid* reg 23(2). Such a person is liable on summary conviction to a fine not exceeding level 5 on the standard scale: see reg 23(2). See also note 28 *supra*. As to the standard scale see PARA 6 note 22 *ante*.

UPDATE

165 Advertising to health professionals

NOTE 23--National public health authorities of member states may lawfully offer financial incentives to doctors to prescribe certain medicines in preference to others: Case C-62/09 *R (on the application of Association of the British Pharmaceutical Industry) v Medicines and Healthcare Products Regulatory Agency (the NHS Confederation (Employers) Co Ltd intervening)* [2010] All ER (D) 142 (Apr), ECJ.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(10) ADVERTISING/166. Power of licensing authority to require copies of advertisements.

166. Power of licensing authority to require copies of advertisements.

The licensing authority¹ may serve² a notice requiring any commercially interested party³ who has issued or caused to be issued any advertisement⁴, including any data sheet⁵, or any person⁶ who has done so at the request or with the consent of a commercially interested party⁷, to furnish to the authority copies⁸ of any advertisement relating to medicinal products⁹, or to medicinal products of a description¹⁰ or falling within a class specified in the notice, which he has issued or caused to be issued within the preceding 12 months¹¹. Any person who without reasonable excuse fails to comply with any requirement imposed on him by such a notice is guilty of an offence¹².

1 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

2 As to the service of notices see PARA 37 note 8 ante.

3 For the meaning of 'commercially interested party' see PARA 159 note 2 ante.

4 For the meaning of 'advertisement', and as to references to 'the issue of an advertisement', see PARA 157 ante.

5 For the meaning of 'data sheet' see PARA 164 note 3 ante.

6 For the meaning of 'person' see PARA 21 note 7 ante.

7 As to references to the request or consent of a commercially interested party see PARA 159 note 3 ante.

8 The number of copies must not exceed 12, and they must be furnished within such time as may be specified in the notice: Medicines Act 1968 s 97(1).

9 For the meaning of 'medicinal product' see PARA 7 ante.

10 As to the description of medicinal products see PARA 7 note 33 ante.

11 Medicines Act 1968 s 97(1). For the meaning of 'month' see PARA 22 note 15 ante.

12 Ibid s 97(2) (amended by virtue of the Criminal Justice Act 1982 ss 37, 46). Such a person is liable on summary conviction to a fine not exceeding level 3 on the standard scale: Medicines Act 1968 s 97(2) (as so amended). As to the standard scale see PARA 6 note 22 ante. As to enforcement, prosecution, defences and related matters see PARA 176 et seq post.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(10) ADVERTISING/167. Monitoring of advertisements.

167. Monitoring of advertisements.

The health ministers¹ must consider any complaint² made to them, that an advertisement³, whether or not it has yet been published⁴, may be in breach of the advertising regulations⁵.

In relation to a complaint made to them that an advertisement, whether or not it has yet been published, may be in breach of any provision of the advertising regulations prohibiting certain material in advertisements to the public⁶, or any of the provisions thereof relating to advertising to health professionals⁷, and where they and the complainant so agree within a reasonable time, the health ministers must select a body which appears to them to be a self-regulatory body which deals with complaints about advertisements of that type, and refer the complaint to that body, and that body may consider the complaint⁸. In the absence of any such agreement within a reasonable time⁹ or if, where there is such agreement, the body selected by them has not within a reasonable time dealt with the complaint adequately¹⁰, the health ministers must consider the complaint¹¹.

If, having considered¹² an advertisement (whether or not a complaint has been made), the health ministers consider that that advertisement is in breach of the advertising regulations, they may bring proceedings for an injunction, in which proceedings they may also apply for an interim injunction, against any person appearing to them to be concerned or likely to be concerned with the publication of that advertisement¹³. Before granting an injunction, the court must have regard to all the interests involved and in particular the public interest¹⁴. An injunction may relate not only to a particular advertisement but to any advertisement in similar terms or likely to convey a similar impression¹⁵, and may prohibit the publication or further publication of an advertisement¹⁶. Where the court has granted an injunction, other than an interim injunction, the health ministers may require any person against whom the injunction has been granted to publish within a specified time, in such form as the health ministers consider adequate, the decision, in full or in part, to grant the injunction¹⁷, and a corrective statement in relation to the advertisement in respect of which the injunction was granted¹⁸.

The health ministers may serve a notice¹⁹ in writing in respect of any relevant medicinal product, or in respect of relevant medicinal products of any class or description, on any person appearing to them to be concerned, or likely to be concerned, with the publication of an advertisement, requiring that person to furnish to them within such period as may be specified in the notice a copy of any advertisement which he has published or proposes to publish²⁰. If the health ministers, having considered an advertisement so furnished to them or otherwise obtained by them, are minded to make a determination that the advertisement, if published, would be in breach of the advertising regulations, they may serve a notice²¹ on any person appearing to them to be concerned or likely to be concerned with the publication of the advertisement, and the notice may require that person to refrain from publishing that advertisement until the notice has been withdrawn by the health ministers²². If, however, upon further consideration, in particular of any representations made to them²³, the health ministers decide that the advertisement, if published, would not be in breach of the advertising regulations, they must serve a notice on the person on whom they had previously served notice, informing him of that decision²⁴ and withdrawing the notice previously served in respect of that advertisement²⁵. If, upon further consideration, in particular of any representations made to them²⁶, the health ministers make a determination that the advertisement, if published, would be in breach of the advertising regulations, they must serve a notice on the person on whom they had previously served notice stating the reasons for the determination²⁷.

and withdrawing the notice previously served in respect of that advertisement²⁸, and the notice may require him to refrain from publishing that advertisement²⁹.

Any person who fails to comply with any requirement imposed on him by a notice³⁰ is guilty of an offence³¹. Any person who fails to comply with any requirement imposed on him³² in respect of the publication of a determination and a corrective statement is guilty of an offence³³.

1 For the meaning of 'the health ministers' see PARA 3 note 4 ante; definition applied by the Medicines (Monitoring of Advertising) Regulations 1994, SI 1994/1933, reg 2(3). In the case of anything falling to be done by them under the Medicines (Monitoring of Advertising) Regulations 1994, SI 1994/1933 (as amended), 'the health ministers' means any one of them acting alone or any two or more of them acting jointly: reg 2(3).

2 le other than a complaint to which *ibid* reg 5 (see the text to notes 6-11 *infra*) applies or which it is the duty of OFCOM to consider: reg 4(1) (amended by SI 2003/3093). 'OFCOM' means the Office of Communications established by the Office of Communications Act 2002 s 1(1) (see TELECOMMUNICATIONS vol 97 (2010) PARA 2): Medicines (Monitoring of Advertising) Regulations 1994, SI 1994/1933, reg 2(1) (definition added by SI 2003/3093). Complaints relating to certain broadcast advertisements are to be referred to OFCOM: see the Medicines (Monitoring of Advertising) Regulations 1994, SI 1994/1933, regs 9, 11 (reg 9 substituted, and reg 11 amended, by SI 2003/3093).

3 'Advertisement' has the meaning assigned to it by the Medicines Act 1968 s 92 (as amended) (see PARA 157 ante), except that (provided that it makes no product claim) reference material, a factual, informative statement or announcement, a trade catalogue or a price list is not to be taken to be an advertisement, and an advertisement includes a representation; and 'representation' has the meaning assigned to it by s 92 (as amended) (see PARA 158 note 14 ante) except that it does not include the making of a factual, informative statement or announcement which includes no product claim: Medicines (Monitoring of Advertising) Regulations 1994, SI 1994/1933, reg 2(2). The Medicines (Monitoring of Advertising) Regulations 1994, SI 1994/1933 (as amended) apply only to an advertisement for a product, substance or article for human use which is:

73 (1) a medicinal product to which EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) (amended by EC Parliament and Council Directive 2002/98 (OJ L033, 8.2.2003, p 30), EC Commission Directive 2003/63 (OJ L159, 27.6.2003, p 46), EC Parliament and Council Directive 2004/24 (OJ L136, 30.4.2004, p 85) and EC Parliament and Council Directive 2004/27 (OJ L136, 30.4.2004, p 34)) applies;

74 (2) a substance or article to which that Directive applies, and specified in an order made under the Medicines Act 1968 ss 104, 105 (see PARA 9 ante), or in regulations made under the European Communities Act 1972 s 2(2), which direct that the Medicines Act 1968 Pt VI (ss 92-97) (as amended) or any provision of that Part has effect in relation to such substance or article as that Part has effect in relation to medicinal products within the meaning of the Act;

but do not apply to an advertisement for a homoeopathic medicinal product in respect of which there is in force a product licence being a licence of right: Medicines (Monitoring of Advertising) Regulations 1994, SI 1994/1933, reg 2(6) (amended by SI 2002/236; SI 2005/2787). For the meaning of 'substance' see PARA 7 note 1 ante; for the meaning of 'medicinal product' see PARA 7 ante; and for the meaning of 'product licence' see PARA 44 note 5 ante (definitions applied by the Medicines (Monitoring of Advertising) Regulations 1994, SI 1994/1933, reg 2(1)). For the meaning of 'United Kingdom' see PARA 7 note 3 ante. As to licences of right see PARA 12 note 23 ante.

4 'Publication' in relation to an advertisement means the dissemination or issue of that advertisement, whether orally, in writing, by means of television or radio broadcast, or in any other way; and 'publish' must be construed accordingly: *ibid* reg 2(1) (definition amended by SI 1999/267). For the meaning of 'writing' see PARA 21 note 6 ante; definition applied by the Medicines (Monitoring of Advertising) Regulations 1994, SI 1994/1933, reg 2(1).

5 *Ibid* reg 4(1). The health ministers must not proceed with the consideration of any complaint which appears to them to be frivolous or vexatious: reg 4(2). In exercising the powers conferred on them, the health ministers must have regard to all the interests involved and in particular the public interest: reg 4(3). 'The advertising regulations' means the Medicines (Advertising) Regulations 1994, SI 1994/1932 (as amended) (see PARAS 163, 165 ante): Medicines (Monitoring of Advertising) Regulations 1994, SI 1994/1933, reg 2(1).

The Medicines Act 1968 ss 107-108 (see PARAS 79, 168 post), ss 111-116 (see PARAS 169-173 post), ss 118, 119 (see PARAS 174-175 post), ss 121-126 (see PARAS 179-181, 183-184 post), s 127 (see PARA 37 note 8 ante) and Sch 3 (see PARA 171 post) apply for the purposes of the Medicines (Monitoring of Advertising) Regulations 1994, SI 1994/1933 (as amended) as they apply for the purposes of the Act: Medicines (Monitoring of Advertising) Regulations 1994, SI 1994/1933, reg 12 (added by SI 1999/267).

6 le the Medicines (Advertising) Regulations 1994, SI 1994/1932, reg 9: see PARA 163 ante.

7 Medicines (Monitoring of Advertising) Regulations 1994, SI 1994/1933, reg 5(1). The provisions of the advertising regulations relating to advertising to health professionals are the Medicines (Advertising) Regulations 1994, SI 1994/1932, Pt IV (regs 13-21) (as amended): see PARA 165 ante.

8 Medicines (Monitoring of Advertising) Regulations 1994, SI 1994/1933, reg 5(2). Neither the health ministers nor the body selected by them must proceed with the consideration of any complaint which appears to them or to it to be frivolous or vexatious: reg 5(4).

9 Ibid reg 5(3)(a).

10 Ibid reg 5(3)(b).

11 Ibid reg 5(3). See also note 8 supra.

12 Ie in accordance with ibid regs 4(1), 5(3): see the text to notes 5, 11 supra.

13 Ibid reg 6. As to interim injunctions see CIVIL PROCEDURE vol 11 (2009) PARAS 315-316. Proceedings must be brought in the High Court (reg 3(1)), and the health ministers (whether one of them acting alone or two or more of them acting jointly) may, institute civil proceedings in their own name (reg 3(3)). As to the High Court of Justice in England and Wales see COURTS vol 10 (Reissue) PARA 602 et seq. The Medicines (Monitoring of Advertising) Regulations 1994, SI 1994/1933 (as amended) are without prejudice to the availability of any criminal proceedings which may be taken under the Medicines Act 1968 or the advertising regulations: Medicines (Monitoring of Advertising) Regulations 1994, SI 1994/1933, reg 3(2).

14 Ibid reg 7(1). In considering an application for an injunction the court may, either on the application of any party to the proceedings or of its own motion, require any person appearing to the court to be responsible for the publication of the advertisement to which the application relates to furnish the court within such time as it allows with evidence as to the accuracy of any factual claim made in the advertisement; and in deciding whether or not to make such a requirement the court must have regard to the legitimate interests of any person who would be the subject of or affected by the requirement: reg 7(4). For the meaning of 'person' see PARA 21 note 7 ante. If such evidence is not furnished to it, or if it considers such evidence inadequate, the court may consider the factual claim inaccurate: reg 7(5). The court must not refuse to grant an injunction for lack of evidence that the publication or anticipated publication of the advertisement in question has given rise to loss or damage to any person (reg 7(6)(a)), or the person responsible for the advertisement intended it to be in breach of the advertising regulations, or failed to exercise proper care to prevent its being in breach of those regulations (reg 7(6)(b)).

15 Ibid reg 7(2). Where the court grants an injunction, it must give reasons in detail for the granting of the injunction, and the health ministers must communicate those reasons in writing to the person against whom the injunction has been granted, referring to any remedy available in the court and any time limit which must be met in order for any such remedy to be available: reg 7(7).

16 Ibid reg 7(3). See also note 15 supra.

17 Ibid reg 8(1)(a).

18 Ibid reg 8(1)(b). If any person fails within the time specified to publish any statement which the health ministers may require, the health ministers may certify that failure to the court: reg 8(2). Where a person's failure is so certified, the court may enquire into the matter: reg 8(3). Where the court conducts such an enquiry and is satisfied that a person has failed within the time specified to publish any statement which the health ministers may require, it may, after hearing any witness produced against, or on behalf of, the person concerned (reg 8(4)(a)), and considering any statement offered in his defence (reg 8(4)(b)), deal with him in any manner that would be available to it had he been in contempt of court (reg 8(4)). As to contempt of court see CONTEMPT OF COURT.

19 Where the health ministers serve such a notice on a person, the notice must state the health ministers' reasons for requiring that person to furnish the advertisement and for requiring him (if the notice does) to refrain from publishing it: ibid reg 13, Schedule para 2 (reg 13, Schedule added by SI 1999/267). As to the service of notices see PARA 37 note 8 ante; provisions applied by the Medicines (Monitoring of Advertising) Regulations 1994, SI 1994/1933, reg 12 (as added: see note 5 supra).

20 Ibid Schedule para 1(a) (as added: see note 19 supra). Alternatively, in respect of an advertisement which a person proposes to publish, the notice may specify the number of days before the proposed publication date by which the advertisement must be furnished (Schedule para 1(b)(i) (as so added)), and the period during which the requirement must continue, such period not to exceed 12 months (Schedule para 1(b)(ii) (as so added)). For the meaning of 'month' see PARA 22 note 15 ante. The notice under Schedule para 1(a) (as added) or Schedule para 1(b) (as added) may require the person to refrain from publishing any advertisement required

to be furnished during such period as may be specified in the notice unless that notice has been withdrawn by the health ministers: Schedule para 1 (as so added).

21 The notice must state: (1) that they are minded to make a determination that the advertisement, if published, would be in breach of the advertising regulations (ibid Schedule para 3(a) (as added: see note 19 supra)); (2) the reasons why they are minded to make that determination (Schedule para 3(b) (as so added)); (3) that if such a determination is made, that person may be required to refrain from publishing that advertisement by a notice served under Schedule para 5 (as added) (see the text to notes 26-29 infra) (Schedule para 3(c) (as so added)); and (4) that the person on whom the notice is served has 21 days from the date of the notice in which to make written representations that the proposed determination should not be made (Schedule para 3(d) (as so added)).

22 Ibid Schedule para 3 (as added: see note 19 supra).

23 Ie under ibid Schedule para 3(d) (as added): see note 21 supra.

24 Ibid Schedule para 4(a) (as added: see note 19 supra).

25 Ibid Schedule para 4(b) (as added: see note 19 supra). The notice to be withdrawn is that previously served under Schedule para 3 (as added): see the text to notes 21-22 supra.

26 Ie under ibid Schedule para 3(d) (as added): see note 21 supra.

27 Ibid Schedule para 5(a) (as added: see note 19 supra).

28 Ibid Schedule para 5(b) (as added: see note 19 supra). The notice to be withdrawn is that previously served under Schedule para 3 (as added): see the text to notes 21-22 supra.

29 Ibid Schedule para 5 (as added: see note 19 supra). Where the health ministers have prohibited the publication of an advertisement under this provision and that advertisement has previously been published, they may require any person against whom the prohibition has been imposed to publish within a specified time in such form as the health ministers consider appropriate: (1) the reasons for the determination (as notified to them by the health ministers under Schedule para 5(a) (as added) (see the text to note 27 supra), in full or in part (whichever the health ministers require) (Schedule para 6(a) (as so added)); and (2) a corrective statement in relation to the advertisement in respect of which the prohibition has been imposed (Schedule para 6(b) (as so added)).

30 Ie a notice under ibid Schedule para 1, 3 or 5 (as added): see the text to notes 19-22, 26-29 supra.

31 Ibid Schedule para 7 (as added: see note 19 supra). Such a person is liable on summary conviction to a fine not exceeding the statutory maximum (Schedule para 7(a) (as so added; and amended by SI 1999/784)), or on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both (Medicines (Monitoring of Advertising) Regulations 1994, SI 1994/1933, Schedule para 7(b) (as so added)). As to the statutory maximum see PARA 32 note 3 ante.

32 Ie under ibid Schedule para 6 (as added): see note 29 supra.

33 Ibid Schedule para 8 (as added: see note 19 supra). Such a person is liable on summary conviction to a fine not exceeding level 5 on the standard scale: see Schedule para 8 (as so added). As to the standard scale see PARA 6 note 22 ante.

UPDATE

163 Advertising to the public

NOTE 3--Head (1) Directive 2001/83: further amended by European Parliament and EC Council Regulations 1901/2006 (OJ L378, 27.12.2006, p 1), 1394/2007 (OJ L324, 10.12.2007, p 121) and European Parliament and EC Council Directive 2008/29 (OJ L81, 20.3.2008, p 51).

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(11) ENFORCEMENT AND OFFENCES

(i) Enforcement, Sampling and Forfeiture

168. Enforcement authorities.

It is the duty of the appropriate minister¹ to enforce or to secure the enforcement of the provisions of the Medicines Act 1968 and any regulations or orders made under it². For the purpose of performing that duty in relation to certain statutory provisions and regulations³, he must, in respect of each area for which there is a drugs authority⁴, make arrangements or give directions by which the Pharmaceutical Society⁵ or the drugs authority for that area or both have power or are under a duty concurrently with him to enforce those provisions and regulations to such extent as the arrangements or directions may provide⁶.

Regulations⁷ made by the Secretary of State may provide: (1) that any of certain bodies⁸ as may be specified is either generally or in respect of a specified area to have power concurrently with the appropriate minister, or to be under a duty concurrently with him, to enforce certain of the regulations⁹ regulating dealings with medicinal products¹⁰; and (2) that, in respect of each area for which there is a drugs authority, the Pharmaceutical Society or the drugs authority for that area or both are to have power concurrently with the appropriate minister or to be under a duty concurrently with him to enforce the provisions¹¹ as to the sale of medicinal products on a general sale list and by means of automatic machines¹². The Pharmaceutical Society is under a duty, concurrently with the appropriate minister, to enforce certain provisions¹³; and every county, county borough, metropolitan district and London borough council and the Common Council of the City of London is under a duty concurrently with the appropriate minister to enforce certain provisions¹⁴ as to animal feeding stuffs¹⁵.

However, no duty or power conferred or imposed by or under any of these provisions¹⁶ on any body other than the appropriate minister may be performed or is exercisable in relation to any hospital¹⁷, so much of any premises as is used by a practitioner¹⁸ for carrying on his practice¹⁹, or so much of any other premises as is used for veterinary medicine or veterinary surgery for the purposes of any institution²⁰.

If the appropriate minister is satisfied, after making such inquiry as he thinks fit, that the Pharmaceutical Society or any other body on which a duty to enforce any provisions is imposed²¹ has, in relation to any matter, failed to perform that duty, and that the public interest requires that the provisions in question should be enforced, he may determine that he will himself enforce those provisions in relation to that matter²².

1 'The appropriate minister' means the Secretary of State: see the Medicines Act 1968 s 108(11) (amended by the Secretary of State for Social Services Order 1968, SI 1968/1699, arts 2, 5(4)); and the Ministry of Agriculture, Fisheries and Food (Dissolution) Order 2002, SI 2002/794, art 2. As to the Secretary of State see PARA 3 note 3 ante. So far as exercisable in relation to Wales, ministerial functions under the Medicines Act 1968 s 108 (as amended) are transferred to the National Assembly for Wales: National Assembly for Wales (Transfer of Functions) Order 1999, SI 1999/672, art 2, Sch 1. As to the National Assembly for Wales see CONSTITUTIONAL LAW AND HUMAN RIGHTS.

2 Medicines Act 1968 s 108(1). 'Enforcement authority' means any minister or body on whom a duty or power to enforce any provisions of the Medicines Act 1968 or of any regulations or order made thereunder is imposed or conferred by or under s 108 (as amended): s 132(1). In relation to Wales, this definition has effect

as if the reference to a minister included a reference to the National Assembly for Wales: National Assembly for Wales (Transfer of Functions) Order 1999, SI 1999/672, art 2, Sch 1.

3 le: (1) the provisions of any order made under the Medicines Act 1968 s 62(1)(a) (prohibiting, in the interests of safety, the sale or supply of specified medicinal products: see PARA 48 ante) and of s 63(b) (prohibiting the sale or supply of adulterated medicinal products: see PARA 146 ante), ss 64, 65 (prohibiting the sale or supply of medicinal products not of the required quality or which do not comply with specified standards: see PARAS 147-148 ante), s 85(3)-(5) (prohibiting the possession, sale or supply of medicinal products not properly labelled: see PARA 152 ante), s 87(2) (prohibiting the possession, sale or supply of medicinal products not complying with the requirements as to containers: see PARA 154 ante), s 88(3) (prohibiting the possession, sale or supply of medicinal products which contravene any requirements as to distinctive colours, shapes and markings: see PARA 155 ante), and s 89(2) (prohibiting the sale of medicinal products from automatic machines otherwise than in compliance with the information requirements: see PARA 156 ante), in the application of any of these provisions to the retail sale, offer or exposure for retail sale, or possession for the purpose of retail sale, of medicinal products, and to the supply, offer or exposure for supply or possession for the purpose of supply, of medicinal products in circumstances corresponding to retail sale (s 108(2)(a)); (2) the provisions of s 86(2), (3) (prohibiting the possession or supply of leaflets not complying with requirements or likely to mislead: see PARA 153 ante), in their application to the supply, or possession for the purpose of supply, of leaflets with medicinal products sold or to be sold by retail or supplied or to be supplied in circumstances corresponding to retail sale (s 108(2)(b)); and (3) the provisions of ss 93, 94 (both as amended) and regulations made under s 95 (as amended) (governing representations and advertisements relating to medicinal products: see PARAS 158-161 ante) (s 108(2)(c)). As to references to retail sale and selling by retail see PARA 7 note 12 ante. As to references to supplying anything in circumstances corresponding to retail sale see PARA 7 note 13 ante. For the meaning of 'medicinal product' see PARA 7 ante. As to the meaning of 'leaflet' see PARA 153 note 5 ante.

4 'Drugs authority' means as respects each London borough, metropolitan district, county borough or non-metropolitan county, the council of that borough, district, county borough or county; and as respects the City of London (including the Temples), the Common Council of that City: *ibid* s 108(12) (added by the Food Safety Act 1990 s 59(1), Sch 3 para 8; and amended by the Local Government (Wales) Act 1994 s 66(6), Sch 16 para 33(b)); Medicines Act 1968 s 132(1) (definition added by the Food Safety Act 1990 Sch 3 para 11). As to local government areas and authorities in England and Wales see LOCAL GOVERNMENT vol 69 (2009) PARA 22 et seq. As to the London boroughs and their councils see LONDON GOVERNMENT vol 29(2) (Reissue) PARAS 30, 35-39, 59 et seq. As to the Common Council of the City of London see LONDON GOVERNMENT vol 29(2) (Reissue) PARAS 51-55.

5 For the meaning of 'Pharmaceutical Society' see PARA 2 note 9 ante. Any such arrangements made with or directions given to the Pharmaceutical Society, in so far as they relate to the provisions and regulations as to advertisements and representations specified in note 3 head (3) *supra*, must be limited to their enforcement in respect of: (1) any advertisement issued or representation made on or in any premises, ship, aircraft, vehicle, stall or place where medicinal products are sold by retail or are supplied in circumstances corresponding to retail sale (Medicines Act 1968 s 108(3)(a)); and (2) any advertisement displayed on or in close proximity to an automatic machine in which medicinal products are offered or exposed for sale (s 108(3)(b)). For the meaning of 'advertisement' see PARA 157 ante; and for the meaning of 'representation' see PARA 158 note 14 ante.

6 *Ibid* s 108(2) (amended by the Food Safety Act 1990 Sch 3 para 8). As to restrictions on the power of such bodies to bring prosecutions see the Medicines Act 1968 s 125(4); and PARA 183 post.

7 As to the making of regulations see PARA 5 ante.

8 le the Pharmaceutical Society, any drugs authority, any district council which is not a drugs authority, and the overseers of the Inner Temple and the Middle Temple: Medicines Act 1968 s 108(5) (amended by the Local Government Act 1972 s 179(3); and the Food Safety Act 1990 Sch 3 para 8). As to the Inner and Middle Temples see LONDON GOVERNMENT vol 29(2) (Reissue) PARA 32.

9 le regulations under the Medicines Act 1968 s 66: see PARA 6 ante.

10 *Ibid* s 108(4) (amended by the Secretary of State for Social Services Order 1968, arts 2, 5(4)). As to the regulations that have been made see the Medicines (Sale or Supply) (Miscellaneous Provisions) Regulations 1980, SI 1980/1923 (amended by SI 1982/28; SI 1990/1124; SI 1990/2487; SI 1992/2938; SI 1994/2411; SI 1994/3142; SI 1994/3144; SI 1995/3215; SI 1997/1831; SI 1997/2045; SI 1998/1045; SI 1999/644; SI 1999/2510; SI 2000/7; SI 2000/1070; SI 2000/1918; SI 2000/2494; SI 2001/3849; SI 2002/2469; SI 2003/698; SI 2004/696; SI 2004/1771; SI 2005/764; SI 2005/1520; SI 2005/2750).

11 le the provisions of the Medicines Act 1968 ss 53, 54: see PARAS 135-136 ante.

12 *Ibid* s 108(7) (amended by the Secretary of State for Social Services Order 1968 arts 2, 5(4); and the Food Safety Act 1990 Sch 3 para 8).

13 Medicines Act 1968 s 108(6) (amended by the Animal Health and Welfare Act 1984 s 16 (1), Sch 1 para 3). The provisions referred to in the text are: (1) the provisions of the Medicines Act 1968 s 40 and any regulations made thereunder, s 52 (prohibiting the retail sale of products not on a general sale list except in a registered pharmacy: see PARA 134 ante) and s 58 (prohibition of retail sale or administration of prescription only medicines except in accordance with a prescription: see PARA 140 ante), in their application to England and Wales (s 108(6)(a) (as so amended)); (2) the regulations made under ss 60, 61 (s 60 as amended) (restricting the sale of certain medicinal products: see PARAS 143-144 ante), in their application to premises in England and Wales at which medicinal products are sold by retail or are supplied in circumstances corresponding to retail sale (s 108(6)(b)). For the meanings of 'England' and 'Wales' see PARA 7 note 3 ante.

14 Ie any order made under *ibid* s 62(1)(b) (see PARA 48 ante), s 90 (as amended) and any regulations made by virtue of s 90 (as amended): s 108(8)(a), (b).

15 *Ibid* s 108(8) (amended by the Local Government Act 1972 s 272(1), Sch 30; the Local Government Reorganisation (Miscellaneous Provisions) Order 1988, SI 1988/1955, art 2; and the Local Government (Wales) Act 1994 Sch 16 para 33(a)). As to restrictions on the power of such bodies to bring prosecutions see the Medicines Act 1968 s 125(4); and PARA 183 post.

16 Ie *ibid* s 108(2)-(8): see the text to notes 3-15 supra.

17 *Ibid* s 108(9)(a). For the meaning of 'hospital' see PARA 86 note 2 ante.

18 For the meaning of 'practitioner' see PARA 7 note 10 ante.

19 Medicines Act 1968 s 108(9)(b).

20 *Ibid* s 108(9)(c).

21 Ie by or under *ibid* s 108(4)-(8): see the text to notes 7-15 supra.

22 *Ibid* s 108(10). Where under this provision a minister makes a determination in respect of the enforcement of any provision in relation to a particular matter, he is entitled to recover from the Pharmaceutical Society or other body which was under a duty to enforce that provision in relation to that matter any expenses reasonably incurred by that minister in taking steps to enforce that provision in relation to that matter: s 128(5). As to financial matters generally see PARA 11 ante.

UPDATE

168 Enforcement authorities

TEXT AND NOTES--The following provisions come into force on 1 October 2009: SI 2008/2714. The Pharmaceutical Society is under a duty, concurrently with the appropriate minister, to enforce the provisions of the 1968 Act s 72A(4) and (5) (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 910A) in their application to England and Wales: s 108(6A) (added by the Health Act 2006 s 31(1)(b)). The Pharmaceutical Society is under a duty to enforce the other provisions of the 1968 Act s 72A, and any regulations made under them, in their application to England and Wales: s 108(6B) (as added). The appropriate minister is under no duty to enforce those other provisions, or any regulations made under them, in their application to England and Wales: s 108(6C) (as added). Notwithstanding s 108(6C) the appropriate minister is to be treated for the purposes of ss 111-114 (1) as empowered by s 108 to enforce those other provisions, or any regulations made under them, in their application to England and Wales, and (2) to that extent as an enforcement authority in relation to those other provisions or those regulations in their application to England and Wales: s 108(6D) (as added).

NOTES--Certain functions under provisions mentioned in this paragraph are 'relevant functions' for the purposes of the Regulatory Enforcement and Sanctions Act 2008 s 4, Sch 3, see LOCAL GOVERNMENT vol 69 (2009) PARA 733.

TEXT AND NOTES 2, 17, 22--1968 Act s 108(1), (9)(a), (10) amended: Health Act 2006 s 31(1)(a), (c), (d) (in force 1 October 2009: SI 2008/2714).

NOTE 10--SI 1980/1923 further amended: see PARA 6 NOTE 2.

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169. Rights of entry.

Any person duly authorised in writing¹ by an enforcement authority² has a right at any reasonable time, on production, if required, of his credentials: (1) to enter any premises³ for the purpose of ascertaining whether there is or has been, on or in connection with those premises, any contravention⁴ of any provisions of the Medicines Act 1968 or of any regulations or order made under the Act which that authority is required or empowered⁵ to enforce⁶, or generally for the purposes of the performance by the authority of its functions under the Act or under any such regulations or order⁷; (2) to enter any ship, aircraft or hover vehicle⁸ for the purpose of ascertaining whether there is in it any substance⁹ or article imported¹⁰ in contravention of any provisions of the Act or of any regulations or order made under the Act which that authority is required or empowered¹¹ to enforce¹²; (3) to enter any vehicle other than a hover vehicle, any stall or place other than premises, or any home-going ship¹³, for any purpose for which under head (1) above the person so authorised would have a right to enter any premises¹⁴. A justice of the peace¹⁵ may, in certain circumstances¹⁶, by warrant¹⁷ authorise the enforcement authority, or any person duly authorised by it, to enter any premises, if need be by force¹⁸.

Any person duly authorised in writing by the licensing authority¹⁹ has a right at any reasonable time, on production, if required, of his credentials, to enter any premises occupied by an applicant for a licence or certificate²⁰ for the purpose of verifying any statement contained in his application²¹.

Any person entering any property²² by virtue of any of these provisions²³ may take with him such other persons and such equipment as may appear to him to be necessary²⁴. On leaving any such property which he has entered in pursuance of a warrant, he must leave it, if the property is unoccupied or the occupier or other person in charge²⁵ is temporarily absent, as effectively secured against trespass as he found it²⁶.

1 For the meaning of 'writing' see PARA 21 note 6 ante.

2 For the meaning of 'enforcement authority' see PARA 168 note 2 ante.

3 Admission to any premises used only as a private dwelling house may not be demanded as of right by virtue of the Medicines Act 1968 s 111(1)-(3) (see the text to notes 19-21 infra), unless 24 hours' notice of the intended entry has been given to the occupier: s 111(4).

4 For the meaning of 'contravention' see PARA 6 note 21 ante.

5 Ie by or under the Medicines Act 1968 s 108 (as amended): see PARA 168 ante.

6 Ibid s 111(1)(a).

7 Ibid s 111(1)(b).

8 'Hover vehicle' means a vehicle designed to be supported on a cushion of air: ibid s 132(1).

9 For the meaning of 'substance' see PARA 7 note 1 ante.

10 For the meaning of 'import' see PARA 7 note 3 ante.

11 Ie by or under the Medicines Act 1968 s 108 (as amended): see PARA 168 ante.

12 Ibid s 111(2)(a).

13 'Home-going ship' means a ship plying exclusively in inland waters or engaged exclusively in coastal voyages; 'inland waters' means any canal, river, lake, loch, navigation or estuary; and 'coastal voyage' means a voyage which starts and ends in the United Kingdom and does not involve calling at any place outside the United Kingdom: *ibid* s 111(8). For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

14 *Ibid* s 111(2)(b).

15 As to justices of the peace see *MAGISTRATES* vol 29(2) (Reissue) PARA 501 et seq.

16 *Ie* where the justice is satisfied, on sworn information in writing, that there are reasonable grounds for entering any premises for any purpose for which a person authorised by an enforcement authority has a right to enter them under the Medicines Act 1968 s 111(1)-(4) (s 111(5)) and: (1) that admission has been refused or that refusal is apprehended, and that notice of intention to apply for a warrant has been given to the occupier (s 111(5)(a)); or (2) that an application for admission or the giving of such a notice would defeat the object of the entry (s 111(5)(b)); or (3) that the case is one of urgency (s 111(5)(c)); or (4) that the premises are unoccupied or the occupier is temporarily absent (s 111(5)(d)). In the case of a ship, aircraft, vehicle, stall or place, references to the occupier should be read as references to the master, commander or other person in charge: s 111(6).

17 Any such warrant continues in force for one month: *ibid* s 111(7). For the meaning of 'month' see PARA 22 note 15 ante.

18 *Ibid* s 111(5). This provision also has effect in relation to entering any ship, aircraft, vehicle, stall or place which may be entered under s 111(2) (see the text to notes 8-14 *supra*): s 111(6).

19 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

20 *Ie* a licence or certificate under the Medicines Act 1968 Pt II (ss 6-50) (as amended): see PARA 42 et seq ante.

21 *Ibid* s 111(3). See also note 3 *supra*.

22 *Ie* any premises, ship, aircraft, vehicle, stall or place: *ibid* s 114(1).

23 *Ie* by virtue of *ibid* s 111, whether in pursuance of a warrant or not: s 114(1).

24 *Ibid* s 114(1). For restrictions on the disclosure of information obtained by entry see PARA 174 post; and as to the protection of officers see PARA 175 post. It is an offence to obstruct a person exercising a right of entry: see s 114(2)(a); and PARA 172 post.

25 *Ie* in the case of a ship, aircraft, vehicle, stall or place: *ibid* s 114(1).

26 *Ibid* s 114(1).

UPDATE

169 Rights of entry

TEXT AND NOTES 1-14--Add head (4) for the purpose specified in the third sub-paragraph of art 111(1) of the European Parliament and EC Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) on the Community code relating to medicinal products for human use: 1968 Act s 111(1)(aa) (added by the Medicines for Human Use (Manufacturing Dealing and Miscellaneous Amendments) Regulations 2005, SI 2005/2789).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(11) ENFORCEMENT AND OFFENCES/(i) Enforcement, Sampling and Forfeiture/170. Power to inspect, take samples and seize goods and documents.

170. Power to inspect, take samples and seize goods and documents.

For the purpose of ascertaining whether there is or has been a contravention¹ of the Medicines Act 1968 or of any regulations or order made under the Act which an enforcement authority² is required or empowered to enforce³, any person duly authorised in writing⁴ by that authority has a right to inspect: (1) any substance⁵ or article appearing to him to be a medicinal product⁶; (2) any article appearing to him to be a container⁷ or package⁸ used or intended to be used to contain any medicinal product or to be a label⁹ or leaflet¹⁰ used or intended to be used in connection with a medicinal product¹¹; or (3) any plant or equipment appearing to him to be used or intended to be used in connection with the manufacture¹² or assembly¹³ of medicinal products, and any process of manufacture or assembly of any medicinal products and the means employed, at any stage in the processes of manufacture or assembly, for testing the materials after they have been subjected to these processes¹⁴.

Where for these purposes a person so authorised requires a sample of any substance or article appearing to him to be a medicinal product sold or supplied or intended to be sold or supplied¹⁵, or a substance or article used or intended to be used in the manufacture of a medicinal product¹⁶, if he does not obtain the sample by purchase, he has a right to take a sample¹⁷. He may also for the specified¹⁸ purposes require the production of books and documents and take copies of them¹⁹.

Any person so authorised has a right to seize and detain any substance or article which he has reasonable cause to believe to be a substance or article in relation to which, or by means of which, an offence under the Medicines Act 1968²⁰ is being or has been committed, and any document which he has reasonable cause to believe to be a document which may be required as evidence in proceedings under the Act²¹. He must inform the person from whom the substance or article, including any document, is seized²²; and he must, if requested by that person at the time of seizure or at any subsequent time not later than 21 days afterwards, set aside a sample or treat the substance or article as a sample, whichever he considers more appropriate having regard to the nature of the substance or article²³, unless the nature of the substance or article is such that it is not reasonably practicable to do either of those things²⁴.

Any person duly authorised in writing by the licensing authority²⁵ has the rights conferred by these provisions in relation to things belonging to, or any business carried on by, an applicant for a licence or certificate²⁶, and may exercise those rights for the purpose of verifying any statement contained in the application²⁷.

Where a person claiming to exercise a right by virtue of these provisions is required to produce his credentials, the right is not exercisable by him except on production of those credentials²⁸.

1 For the meaning of 'contravention' see PARA 6 note 21 ante.

2 For the meaning of 'enforcement authority' see PARA 168 note 2 ante.

3 le by or under the Medicines Act 1968 s 108 (as amended): see PARA 168 ante.

4 For the meaning of 'writing' see PARA 21 note 6 ante.

5 For the meaning of 'substance' see PARA 7 note 1 ante.

6 Medicines Act 1968 s 112(1)(a). For the meaning of 'medicinal product' see PARA 7 ante.

7 For the meaning of 'container' see PARA 152 note 4 ante.

8 For the meaning of 'package' see PARA 152 note 4 ante.

9 For the meaning of 'label' see PARA 152 note 4 ante.

10 As to the meaning of 'leaflet' see PARA 153 note 5 ante.

11 Medicines Act 1968 s 112(1)(b).

12 As to the meaning of 'manufacture' see PARA 7 note 2 ante.

13 For the meaning of 'assembly' see PARA 6 note 8 ante.

14 Medicines Act 1968 s 112(1)(c).

15 Ibid s 112(2)(a).

16 Ibid s 112(2)(b).

17 Ibid s 112(2). As to the procedure to be followed where a sample is obtained for these purposes see PARA 171 post. If payment is demanded, a sample obtained under s 112 must be paid for: s 112(9), Sch 3 para 28(1). There is procedure for arbitration in default of agreement as to the value of the sample: see Sch 3 para 28(2). The taking of a sample is deemed to be a sale for the purposes of s 64(1)-(4) (see PARA 147 ante): Sch 3 para 29.

18 Ie the purposes specified by ibid s 112(1): see the text to notes 1-14 supra.

19 See ibid s 112(3). Thus he may require any person carrying on a business which consists of or includes the manufacture, assembly, sale or supply of medicinal products, and any person employed in connection with such a business, to produce any books or documents relating to the business which are in his possession or under his control (s 112(3)(a)), and he may take copies of, or of any entry in, any book or document so produced (s 112(3)(b)). For the meaning of 'person' see PARA 21 note 7 ante. As to the meaning of 'business' see PARA 7 note 11 ante.

20 'Offence under the Medicines Act 1968' includes an offence under any regulations or order made under the Act: s 132(1).

21 Ibid s 112(4). For the purpose of exercising this right, the person having the right may, so far as is reasonably necessary to secure the due observance of the Act and any regulations and order made under it, require any person having authority to do so to break open any container or package or open any vending machine, or to permit him to do so: s 112(5).

22 Ibid s 112(6). In the case of anything seized from a vending machine, he must inform the person whose name and address are stated on the machine as being those of its owner or, if no name and address are stated, the occupier of the premises on which the machine stands or to which it is affixed: s 112(6).

23 Ibid s 113(1), (2).

24 Ibid s 113(1), (3). Where such a sample is set aside, or where a substance or article is treated as a sample, the authorised person must divide it into three parts, each part being marked and sealed or fastened up in such manner as its nature will permit, and one such part must be supplied to the person making the request for sampling: s 113(1), (4). The procedure laid down in Sch 3 paras 10-12, 15-27 (see PARA 171 post) must then be followed in respect of the remaining two parts of the sample, substance or article: see s 113(5).

25 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

26 Ie a licence or certificate under the Medicines Act 1968 Pt II (ss 6-50) (as amended): see PARA 42 et seq ante.

27 Ibid s 112(7). Where by virtue of s 112(7) a person exercises any right specified in s 112(4) (see the text to notes 20-21 supra), he is subject to the duty imposed by s 112(6) (see the text to note 22 supra): s 112(7). The provisions of s 113 (see the text to notes 23-24 supra) also apply in such a case: s 113(1).

28 Ibid s 112(8). It is an offence wilfully to obstruct an authorised person acting in pursuance of s 112: see PARA 172 post. As to the protection of officers see PARA 175 post.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(11) ENFORCEMENT AND OFFENCES/(i) Enforcement, Sampling and Forfeiture/171. Sampling and analysis.

171. Sampling and analysis.

Where either by purchase or in the exercise of certain powers¹ a person, referred to as a 'sampling officer', authorised by an enforcement authority² obtains a sample of any substance³ or article for the purpose of ascertaining whether there is or has been, in connection with that substance or article, any contravention⁴ of the provisions of the Medicines Act 1968 or of any regulations or order made under the Act which the authority is required or empowered⁵ to enforce⁶, or otherwise for any purpose connected with the authority's performance of its functions under the Act, any regulations or order⁷, he must deal with that sample in accordance with a specified procedure⁸.

The sampling officer must forthwith divide the sample into three parts, each to be marked and sealed or fastened up in such manner as its nature permits⁹. One part must be supplied to the seller¹⁰, owner¹¹, consignee¹² or consignor¹³ of the substance or article from which the sample was taken¹⁴, who must be informed that the sample has been obtained for the purpose of analysis¹⁵ or other appropriate examination¹⁶. Where it appears to the sampling officer that any such person is not the manufacturer¹⁷ or assembler¹⁸ named on the container¹⁹ of the substance or article, that manufacturer or assembler must also, within three days, be notified that the sample has been obtained and informed from whom it was purchased or from where it was obtained²⁰. Unless the sampling officer decides not to submit the sample for analysis or examination, one of the remaining parts of the sample must be retained for future comparison²¹, and the third part must be submitted to the public analyst²² for the area, or in certain circumstances to other specified persons, for analysis²³.

The analyst must send to the sampling officer a certificate in the prescribed form²⁴, specifying the results of the analysis²⁵. On payment of the prescribed fee²⁶ to the relevant enforcement authority, the person to whom a part of the sample is required to be supplied is entitled to be supplied with a copy of the certificate as to the result of the analysis or examination²⁷. In any proceedings for an offence under the Act²⁸, this certificate is sufficient evidence²⁹ of the facts stated in it, unless the other party requires the person who issued the certificate to be called as a witness³⁰. In any such proceedings, the court may cause the part of the sample retained for future comparison³¹ to be sent for analysis to the government chemist or to be sent for other appropriate examination to the person having the management or control of a laboratory specified by the court³².

A person, other than a person so authorised by an enforcement authority, who has purchased a medicinal product may submit a sample of it for analysis to the public analyst for the area in which the product was purchased, or, if for the time being there is no such public analyst, to the public analyst for another area³³.

The ministers may by order³⁴ modify the sampling provisions³⁵; and the agriculture ministers³⁶ may provide by regulations³⁷ that the provisions relating to inspection, taking samples, seizing goods and documents³⁸, sampling³⁹, sampling of articles seized⁴⁰, and the analysis of samples submitted by persons other than sampling officers⁴¹, are to have effect in relation to animal feeding stuffs subject to specified modifications⁴².

A drugs authority⁴³ or a non-metropolitan district council⁴⁴ may provide facilities for the microbiological examination of drugs⁴⁵.

1 le conferred by the Medicines Act 1968 s 112: see PARA 170 ante.

- 2 For the meaning of 'enforcement authority' see PARA 168 note 2 ante.
- 3 For the meaning of 'substance' see PARA 7 note 1 ante.
- 4 For the meaning of 'contravention' see PARA 6 note 21 ante.
- 5 Ie under the Medicines Act 1968 s 108 (as amended): see PARA 168 ante.
- 6 Ibid s 112(9), Sch 3 para 1(1)(a).
- 7 Ibid Sch 3 para 1(1)(b).
- 8 Ibid Sch 3 para 1.
- 9 Ibid Sch 3 para 2. Where a sample consists of substances or articles enclosed in unopened containers, and to open them and divide the contents is impracticable or might affect the composition of the contents or impede the analysis or examination, the sampling officer may divide the sample into parts by dividing the unopened containers into three lots: Sch 3 para 11. For the meaning of 'container' see PARA 152 note 4 ante. For the meaning of 'composition' see PARA 44 note 14 ante.
- 10 Ibid Sch 3 paras 3, 6. This applies where the sample was purchased otherwise than from an automatic machine (Sch 3 para 3), or, in a case not falling within Sch 3 paras 3-5, if the sample was obtained at the request or with the consent of a purchaser (Sch 3 para 6).
- 11 Ibid Sch 3 paras 4, 8. This applies if the sample was obtained from an automatic machine and a person's name and an address in the United Kingdom are stated on the machine as being those of the owner of the machine: Sch 3 para 4(a). For the meaning of 'United Kingdom' see PARA 7 note 3 ante. In any other case where the sample is so obtained, one part of the sample must be supplied to the occupier of the premises on which the machine stands or to which it is affixed: Sch 3 para 4(b). Further, in any case not falling within Sch 3 paras 3-7, one part of the sample must be supplied to the person appearing to the sampling officer to be the owner of the substance or article from which the sample was taken: Sch 3 para 8.
- 12 Ibid Sch 3 para 5. This applies if the sample is of goods consigned from outside the United Kingdom and was taken before delivery to the consignee: Sch 3 para 5.
- 13 Ibid Sch 3 para 7. This applies in a case not falling within any of the provisions of Sch 3 paras 3-6, if the sample was taken in transit: Sch 3 para 7.
- 14 See ibid Sch 3 paras 3-8; and the text to notes 10-13 supra. The provisions of s 127 (see PARA 37 note 8 ante) apply to the supply of parts of samples as they apply to the service of documents: Sch 3 para 12.
- 15 'Analysis' includes microbiological assay, but no other form of biological assay; and 'analyse' has a corresponding meaning: ibid s 132(1). As to facilities for microbiological examination of drugs see the text to notes 43-45 infra.
- 16 Ibid Sch 3 para 9. If after reasonable inquiry the sampling officer is unable to ascertain the name of a person to whom or the address at which this part of the sample ought to be supplied, he may retain it: Sch 3 para 13. For the meaning of 'person' see PARA 21 note 7 ante.
- 17 As to the meaning of 'manufacture' see PARA 7 note 2 ante.
- 18 As to the meaning of 'assembler' cf para 6 note 8 ante.
- 19 For the meaning of 'container' see PARA 152 note 4 ante.
- 20 Medicines Act 1968 Sch 3 para 14.
- 21 Ibid Sch 3 para 10(a).
- 22 'Public analyst' has the meaning set out in the Food Safety Act 1990 s 27 (see FOOD vol 18(2) (Reissue) PARA 268): Medicines Act 1968 Sch 3 para 1(2) (amended by the Food Safety Act 1990 s 59(1), Sch 3 para 12).
- 23 See the Medicines Act 1968 Sch 3 paras 10(b), 15-17. The person to whom the sample is submitted must analyse or examine it, or have it analysed or examined under his direction, as soon as practicable: Sch 3 para 18(1). If he is a public analyst and he determines that for any reason an effective analysis cannot be performed by him or under his direction, he must send it to the public analyst for some other area for analysis by him or under his direction as soon as practicable: Sch 3 para 18(2).

24 le in the form prescribed by the ministers: *ibid* Sch 3 para 19(3). For the meaning of 'prescribed' see *PARA* 56 note 3 *ante*. For the meaning of 'the ministers' see *PARA* 3 note 3 *ante*. As to the regulations that have been made see the Medicines (Certificates of Analysis) Regulations 1977, SI 1977/1399.

25 See the Medicines Act 1968 Sch 3 para 19(1), (2).

26 Any regulations prescribing a fee must be made by the ministers: *ibid* Sch 3 para 20(2). As to the regulations that have been made see the Medicines (Certificates of Analysis) Regulations 1977, SI 1977/1399.

27 Medicines Act 1968 Sch 3 para 20(1).

28 For the meaning of 'offence under the Medicines Act 1968' see *PARA* 170 note 20 *ante*. As to offences and proceedings under the Act see *PARA* 176 *et seq post*.

29 As to what is sufficient evidence see *CIVIL PROCEDURE* vol 11 (2009) *PARA* 767.

30 Medicines Act 1968 Sch 3 para 21. A document produced by one of the parties to the proceedings which has been supplied to him by the other party as being a copy of such a certificate is also sufficient evidence of the facts stated: Sch 3 para 22. If, in proceedings before a magistrates' court, a defendant intends to produce such a certificate, or to require the person who issued the certificate to be called as a witness, he must give the other party to the proceedings a notice of his intention, and where he intends to produce such a certificate, a copy of the certificate, at least three clear days before the day on which the summons is returnable: Sch 3 para 23(1). If this provision is not complied with, the court may, if it thinks fit, adjourn the hearing on such terms as it thinks proper: Sch 3 para 23(2). The provisions of Sch 3 paras 21, 22, 24 have effect in respect of such certificates and documents, instead of the similar provisions of the Criminal Justice Act 1967 s 9 (as amended): Medicines Act 1968 Sch 3 para 26. As to magistrates courts see *MAGISTRATES*.

31 Where either party to the proceedings so requests, the court must cause the sample to be sent for analysis or examination and, in the absence of any such request, it may do so if it thinks fit: *ibid* Sch 3 para 24(1).

32 *Ibid* Sch 3 para 24(1). The cost of the analysis or examination must be paid by the prosecutor or defendant, as the court may order: Sch 3 para 25.

33 *Ibid* s 115(1). The provisions of Sch 3 paras 2-13 (see the text to notes 9-16 *supra*) apply to such a sample as if the person submitting the sample were the sampling officer: s 115(2).

34 As to the making of orders see *PARA* 5 *ante*.

35 Medicines Act 1968 Sch 3 para 27. The sampling provisions are contained in Sch 3 paras 1-26.

36 For the meaning of 'the agriculture ministers' see *PARA* 3 note 5 *ante*.

37 As to the making of regulations see *PARA* 5 *ante*.

38 le the Medicines Act 1968 s 112: see *PARA* 170 *ante*.

39 le *ibid* Sch 3.

40 le *ibid* s 113: see *PARA* 170 *ante*.

41 le *ibid* s 115: see the text to note 33 *supra*.

42 *Ibid* s 117(1). For the meaning of 'animal feeding stuffs' see *PARA* 7 note 2 *ante*. The application of the provisions of s 115 may be replaced by provisions in the regulations corresponding to the Agriculture Act 1970 ss 75, 78: see Medicines Act 1968 s 117(5A) (added by the Animal Health and Welfare Act 1984 s 15). As to the regulations see the Medicines (Feeding Stuffs Limits of Variation) Order 1976, SI 1976/31; the Medicines (Animal Feeding Stuffs) (Enforcement) Regulations 1985, SI 1985/273 (amended by SI 1989/2324; SI 1996/1261).

43 For the meaning of 'drugs authority' see *PARA* 168 note 4 *ante*.

44 As to non-metropolitan district councils see *LOCAL GOVERNMENT* vol 69 (2009) *PARA* 130.

45 Medicines Act 1968 s 115A (added by the Food Safety Act 1990 s 59 (1), Sch 3 para 10).

UPDATE

171 Sampling and analysis

NOTES--Certain functions under provisions mentioned in this paragraph are 'relevant functions' for the purposes of the Regulatory Enforcement and Sanctions Act 2008 s 4, Sch 3, see LOCAL GOVERNMENT vol 69 (2009) PARA 733. Certain persons or indorsements mentioned in this paragraph are specified for the purposes of Regulatory Enforcement and Sanctions Act 2008 s 37, Schs 5, 6 (meaning of 'regulator' for the purposes of imposing civil sanctions), see ADMINISTRATIVE LAW vol 1(1) (2001 Reissue) PARA 196A.

NOTES 24, 26--SI 1977/1399 amended: SI 2005/2745.

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172. Offences related to enforcement.

Any person who wilfully obstructs a person acting in pursuance of the Medicines Act 1968 and duly authorised so to act by an enforcement authority¹, or who wilfully fails to comply with any requirement properly made to him by a person so acting under the provisions² relating to inspection, the taking of samples and the seizing of goods and documents³, or who without reasonable cause fails to give to a person so acting any other assistance or information which that person may reasonably require of him for the performance of his functions under the Act⁴, is guilty of an offence⁵. If any person in giving such information makes any statement which he knows to be false he is guilty of an offence⁶.

1 Medicines Act 1968 s 114(2)(a). For the meaning of 'enforcement authority' see PARA 168 note 2 ante.

2 Ie under ibid s 112: see PARA 170 ante.

3 Ibid s 114(2)(b).

4 Ibid s 114(2)(c). Nothing in s 114 is to be construed as requiring a person to answer any question or give any information if to do so might incriminate that person or (where that person is married) the husband or wife of that person: s 114(4). As from a day to be appointed, this provision is amended so as to extend also to civil partners: see s 114(4) (prospectively amended by the Civil Partnership Act 2004 s 261(1), Sch 27 para 32).

5 Medicines Act 1968 s 114(2) (amended by virtue of the Criminal Justice Act 1982 ss 37, 46). Such a person is liable on summary conviction to a fine not exceeding level 3 on the standard scale: Medicines Act 1968 s 114(2) (as so amended). As to the standard scale see PARA 6 note 22 ante.

6 Ibid s 114(3). See also note 4 supra. Such a person is liable on summary conviction to a fine not exceeding the prescribed sum (s 114(3)(a) (amended by virtue of the Magistrates' Courts Act 1980 s 32(2))), or on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both (Medicines Act 1968 s 114(3)(b)). As to the prescribed sum see PARA 32 note 3 ante.

UPDATE

172 Offences related to enforcement

NOTE 4--Day now appointed: SI 2005/3175.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(11) ENFORCEMENT AND OFFENCES/(i) Enforcement, Sampling and Forfeiture/173. Forfeiture of medicinal products and animal feeding stuffs.

173. Forfeiture of medicinal products and animal feeding stuffs.

For the purposes of the statutory provisions as to the forfeiture of goods improperly imported¹, any imported² goods are deemed to be imported contrary to a restriction for the time being in force with respect to them under the Medicines Act 1968³ if they are goods falling within a class⁴ specified in an order⁵ made by the ministers⁶ and the goods are imported in circumstances specified in that order⁷.

For the purposes of offences in relation to exportation of prohibited or restricted goods⁸ any goods are deemed to be exported⁹ contrary to a restriction for the time being in force under the Medicines Act 1968¹⁰ if they are goods falling within a class specified in an order made by the ministers¹¹ and the goods are exported in circumstances specified in that order¹².

1 Ie the provisions of the Customs and Excise Management Act 1979 s 49 (modified, in relation to goods imported through the Channel Tunnel, by the Channel Tunnel (Customs and Excise) Order 1990, SI 1990/2167 (as amended)); see CUSTOMS AND EXCISE vol 12(3) (2007 Reissue) PARA 993.

2 For the meaning of 'import' see PARA 7 note 3 ante.

3 Medicines Act 1968 s 116(1) (amended by the Customs and Excise Management Act 1979 s 177(1), Sch 4 para 12). The effect of this provision is to render the goods liable to forfeiture under the Customs and Excise Management Act 1979 s 49, and presumably the provisions of s 139 (as amended) as to seizure and detention of goods liable to forfeiture are accordingly also applicable. The opening words of the Medicines Act 1968 s 116(1), which refer specifically to the purposes of the Customs and Excise Management Act 1979 s 49 for which the goods are deemed to be improperly imported, would seem, however, to exclude the application of the provisions of s 50 (as amended), which penalises the importation of goods contrary to a restriction in force. In the case of exportation, both the provisions as to forfeiture and those as to penalties are contained in s 68 (as amended) (see the text to notes 8-12 infra). It would therefore seem that, anomalously, the Medicines Act 1968 s 116(2) imposes a penalty for contravention in respect of exports whereas s 116(1) does not do so in respect of imports.

4 Any class of goods specified must consist exclusively of goods appearing to the ministers to be goods which are, or normally are, medicinal products or animal feeding stuffs in which medicinal products have been incorporated: *ibid* s 116(3). For the meaning of 'the ministers' see PARA 3 note 3 ante. For the meaning of 'medicinal product' see PARA 7 ante. For the meaning of 'animal feeding stuffs' see PARA 7 note 2 ante. References to the incorporation of a medicinal product in an animal feeding stuff do not include a reference to it being so incorporated in the course of making a medicinal product; but, subject to that, they include a reference to the incorporation for a medicinal purpose of a substance or article other than a medicinal product, or of a substance in which a medicinal product has been incorporated, in an animal feeding stuff: s 40(11) (substituted by the Animal Health and Welfare Act 1984 s 13(1)). For the meaning of 'a medicinal purpose' see PARA 8 ante. For the meaning of 'substance' see PARA 7 note 1 ante. As to animal feeding stuffs see AGRICULTURAL PRODUCTION AND MARKETING vol 1 (2008) PARA 996 et seq.

5 As to the making of orders see PARA 5 ante. At the date at which this volume states the law, no such order had been made.

6 Medicines Act 1968 s 116(1)(a).

7 *Ibid* s 116(1)(b).

8 Ie the provisions of the Customs and Excise Management Act 1979 s 68 (as amended): see CUSTOMS AND EXCISE vol 12(3) (2007 Reissue) PARA 1029.

9 For the meaning of 'export' see PARA 7 note 4 ante.

10 Medicines Act 1968 s 116(2) (amended by the Customs and Excise Management Act 1979 Sch 4 para 12).

11 Medicines Act 1968 s 116(2)(a).

12 Ibid s 116(2)(b). At the date at which this volume states the law, no such order had been made.

UPDATE

173 Forfeiture of medicinal products and animal feeding stuffs

NOTES--Certain functions under provisions mentioned in this paragraph are 'relevant functions' for the purposes of the Regulatory Enforcement and Sanctions Act 2008 s 4, Sch 3, see LOCAL GOVERNMENT vol 69 (2009) PARA 733.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(11) ENFORCEMENT AND OFFENCES/(i) Enforcement, Sampling and Forfeiture/174. Disclosure of information.

174. Disclosure of information.

If any person discloses to any other person any information with respect to any manufacturing process or trade secret obtained by him in premises which he has entered under his powers of entry¹ or any information obtained by or furnished to him in pursuance of the Medicines Act 1968², then, unless the disclosure was made in the performance of his duty, he is guilty of an offence³.

1 Medicines Act 1968 s 118(1)(a). The powers of entry referred to are the powers under s 111: see PARA 169 ante.

2 Ibid s 118(1)(b).

3 Ibid s 118(1). Such a person is liable on summary conviction to a fine not exceeding the prescribed sum (s 118(2)(a) (amended by virtue of the Magistrates' Courts Act 1980 s 32(2))), or on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both (Medicines Act 1968 s 118(2)(b)). As to the prescribed sum see PARA 32 note 3 ante. Section 118(1) does not apply if the person making the disclosure referred to is, or is acting on behalf of a person who is a public authority for the purposes of the Freedom of Information Act 2000 (see CONFIDENCE AND DATA PROTECTION vol 8(1) (2003 Reissue) PARA 583), and the information is not held by the authority on behalf of another person: Medicines Act 1968 s 118(1A) (added by the Freedom of Information (Removal and Relaxation of Statutory Prohibitions on Disclosure of Information) Order 2004, SI 2004/3363, art 4). As to the prosecution of offences see PARA 183 post.

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175. Protection of officers.

An officer of an enforcement authority¹ is not personally liable in respect of any act done by him in the execution or purported execution of the Medicines Act 1968 and within the scope of his employment² if he did it in the honest belief that his duty under the Act required or entitled him to do it³. Where an action has been brought against an officer of an enforcement authority in respect of an act done by him in the execution or purported execution of the Act, and the circumstances are such that he is not legally entitled to require the enforcement authority to indemnify him, the authority may nevertheless indemnify him against the whole or part of the damages and costs or expenses which he may have been ordered to pay or may have incurred, if it is satisfied that he honestly believed that his duty under the Act required or entitled him to do it⁴.

1 For the meaning of 'enforcement authority' see PARA 168 note 2 ante. Any reference to an officer of such an authority includes a reference to any person who, not being such an officer, is authorised to act in pursuance of the Medicines Act 1968 by such an authority: s 119(3).

2 In the case of a person who is not an officer (see note 1 supra), the reference to the scope of his employment is a reference to the scope of the authorisation under which he acts: *ibid* s 119(3).

3 *Ibid* s 119(1).

4 *Ibid* s 119(2). See also note 1 supra.

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(ii) Offences and Proceedings

176. Offences relating to licences and certificates.

Each of the following persons¹ is guilty of an offence:

- 149 (1) any person who contravenes² any of the provisions as to product licences³, manufacturer's licences⁴, wholesale dealer's licences⁵, medicinal tests on animals⁶, the disposal of animals on which medicinal tests have been carried out⁷, or medicated animal feeding stuffs⁸, or who is in possession of any medicinal product⁹ or animal feeding stuff for the purpose of selling, supplying or exporting¹⁰ it in contravention of any of these provisions¹¹;
- 150 (2) where any medicinal product or animal feeding stuff is imported¹² in contravention of the provisions¹³ as to product licences or medicinal tests on animals or relating to medicated animal feeding stuffs, any person who, otherwise than for the purpose of performing or exercising a duty or power imposed or conferred by or under the Medicines Act 1968 or any other enactment¹⁴, is in possession of the product or feeding stuff knowing or having reasonable cause to suspect that it was so imported¹⁵;
- 151 (3) any person who, being the holder¹⁶ of a product licence or an animal test certificate¹⁷, procures another person to carry out a process in the manufacture¹⁸ or assembly¹⁹ of medicinal products of a description²⁰ to which the licence or certificate relates, and who does not communicate to that person the provisions of the licence or certificate which are applicable to medicinal products of that description²¹ or who, in a case where any of those provisions has been varied²² by a decision of the licensing authority²³, does not communicate the variation to that person within 14 days after notice of the decision has been served on him²⁴;
- 152 (4) any person who, being the holder of a product licence or an animal test certificate, sells or supplies a substance²⁵ or article to which the licence or certificate relates to another person for the purpose of its being incorporated in any animal feeding stuff and who does not communicate to that person any provisions of the licence or certificate which relate to such incorporation, or any instructions required by the licence to be communicated by him to persons to whom the substance or article is sold or supplied for that purpose²⁶;
- 153 (5) the holder of the licence or certificate, where any such provisions are varied by the licensing authority and where, on varying those provisions, the authority serves on the holder a notice requiring him, within such time, not being less than 14 days from the date of service of the notice²⁷, as may be specified in the notice, to take such steps as may be specified for making the variation known either generally or to specified persons or classes of persons, and the holder of the licence or certificate does not comply with the requirements of that notice²⁸;
- 154 (6) any person who, in giving any information which he is required to give to the licensing authority²⁹, makes a statement which he knows to be false in a material particular³⁰;
- 155 (7) any person who, without reasonable excuse, fails to comply with a requirement imposed on him by a notice³¹ to furnish information to the licensing authority³².

Any person guilty of such an offence is liable to a penalty³³.

- 1 For the meaning of 'person' see PARA 21 note 7 ante. As to offences by bodies corporate see PARA 181 post.
- 2 For the meaning of 'contravene' see PARA 6 note 21 ante.
- 3 In the Medicines Act 1968 s 7 (as amended): see PARA 44 ante. For the meaning of 'product licence' see PARA 44 note 5 ante.
- 4 In *ibid* s 8(2): see PARA 46 ante. For the meaning of 'manufacturer's licence' see PARA 46 note 7 ante.
- 5 In *ibid* s 8(3): see PARA 47; ante. For the meaning of 'wholesale dealer's licence' see PARA 47 note 12 ante.
- 6 In *ibid* s 32: see PARA 127 ante. For the meaning of 'medicinal test on animals' see PARA 126 ante.
- 7 In *ibid* s 34: see PARA 129 ante.
- 8 In *ibid* s 40 (repealed). For the meaning of 'animal feeding stuffs' see PARA 7 note 2 ante.
- 9 For the meaning of 'medicinal product' see PARA 7 ante.
- 10 For the meaning of 'export' see PARA 7 note 4 ante.
- 11 Medicines Act 1968 s 45(1) (s 45(1)-(3) amended by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 54, Sch 10 Pt I para 13). The Medicines Act 1968 s 45(1) (as amended) is expressed to be subject to s 46 (as amended): see PARA 177 post.
- 12 For the meaning of 'import' see PARA 7 note 3 ante.
- 13 In the Medicines Act 1968 s 7 (as amended), s 32, s 40 (as substituted).
- 14 For the meaning of 'enactment' see PARA 151 note 6 ante.
- 15 Medicines Act 1968 s 45(2) (as amended: see note 11 *supra*).
- 16 As to references to the holder of a licence or certificate see PARA 66 note 5 ante.
- 17 For the meaning of 'animal test certificate' see PARA 127 note 14 ante.
- 18 As to the meaning of 'manufacture' see PARA 7 note 2 ante.
- 19 For the meaning of 'assembly' see PARA 6 note 8 ante.
- 20 As to the description of medicinal products see PARA 7 note 33 ante.
- 21 Medicines Act 1968 s 45(3)(a) (as amended: see note 11 *supra*).
- 22 As to the variation of licences and certificates see PARAS 70, 78, 132 ante.
- 23 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.
- 24 Medicines Act 1968 s 45(3)(b).
- 25 For the meaning of 'substance' see PARA 7 note 1 ante.
- 26 Medicines Act 1968 s 45(4).
- 27 As to the service of notices see PARA 37 note 8 ante. It seems that the 14-day period is to be reckoned exclusive of the day on which the notice was served and of the day specified in the notice for the taking of the specified steps: see *R v Turner* [1910] 1 KB 346, CCA; *Re Hector Whaling Ltd* [1936] Ch 208.
- 28 Medicines Act 1968 s 45(5).
- 29 In under *ibid* s 44 (as amended): see PARA 70 ante.
- 30 *Ibid* s 45(6).

31 le under *ibid* s 44(2) (as amended): see PARA 70 ante.

32 *Ibid* s 45(7).

33 A person guilty of an offence under heads (1)-(6) in the text is liable on summary conviction to a fine not exceeding the prescribed sum (*ibid* s 45(8)(a) (amended by virtue of the Magistrates' Courts Act 1980 s 32(2))), or on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both (Medicines Act 1968 s 45(8)(b)); and any person guilty of an offence under head (7) in the text is liable on summary conviction to a fine not exceeding level 3 on the standard scale (s 45(9) (amended by virtue of the Criminal Justice Act 1982 ss 38, 46)). As to the prescribed sum see PARA 32 note 3 ante. As to the standard scale see PARA 6 note 22 ante. As to the prosecution of offences see PARA 183 post. As to sentence in respect of an offence under head (1) in the text see *R v Sabeddu* [2001] 1 Cr App Rep (S) 493, CA.

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177. Special defences.

Where the holder¹ of a product licence² or of an animal test certificate³ is charged with an offence against the provisions as to licences and certificates⁴ in respect of any substance⁵ or article which has been manufactured⁶, or, in the case of a medicinal product⁷, manufactured or assembled⁸, to his order by another person⁹ and has been so manufactured or assembled as not to comply with the provisions of that licence or certificate which are applicable to it, it is a defence for him to prove¹⁰ that he had communicated those provisions to that other person¹¹, and that he did not know, and could not by the exercise of reasonable care have discovered, that those provisions had not been complied with¹².

Where the holder of a manufacturer's licence¹³ is charged with an offence against the provisions as to licences and certificates¹⁴ in respect of any medicinal products which have been manufactured or assembled by him, in circumstances where he is not the holder of a product licence or of an animal test certificate which is applicable to those products, but the products were manufactured or assembled to the order of another person, it is a defence for him to prove that he believed, and had reasonable grounds for believing¹⁵, that the other person in question was the holder of a product licence applicable to those products, or of an animal test certificate applicable to them¹⁶, and that the products were manufactured or assembled in accordance with that product licence or certificate¹⁷.

1 As to references to the holder of a licence or certificate see PARA 66 note 5 ante.

2 For the meaning of 'product licence' see PARA 44 note 5 ante.

3 For the meaning of 'animal test certificate' see PARA 127 note 14 ante.

4 Ie an offence under the Medicines Act 1968 s 45 (as amended): see PARA 176 ante.

5 For the meaning of 'substance' see PARA 7 note 1 ante.

6 As to the meaning of 'manufacture' see PARA 7 note 2 ante.

7 For the meaning of 'medicinal product' see PARA 7 ante.

8 For the meaning of 'assemble' see PARA 6 note 8 ante.

9 For the meaning of 'person' see PARA 21 note 7 ante.

10 Medicines Act 1968 s 46(1) (s 46(1), (2) amended by the Medicines for Human Use (Clinical Trials) Regulations 2004, SI 2004/1031, reg 54, Sch 10 Pt I para 14). As to the standard of proof on the accused see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(3) (2006 Reissue) PARA 1372.

11 Medicines Act 1968 s 46(1)(a).

12 Ibid s 46(1)(b).

13 For the meaning of 'manufacturer's licence' see PARA 46 note 7 ante.

14 Ie an offence under the Medicines Act 1968 s 45 (as amended): see PARA 176 ante.

15 Ibid s 46(2) (as amended: see note 10 supra).

16 Ibid s 46(2)(a) (as amended: see note 10 supra).

17 Ibid s 46(2)(b) (as amended: see note 10 supra). As to references to doing anything in accordance with a licence or an animal test certificate see PARA 127 note 13 ante.

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178. Offences relating to dealings, containers, leaflets etc.

Each of the following persons¹ is guilty of an offence²:

- 156 (1) any person who gives a prescription or directions or administers³ a medicinal product⁴ in contravention⁵ of a condition imposed by an order⁶ relating to prescription only products⁷;
- 157 (2) any person who is⁸ an appropriate practitioner⁹ and gives a prescription or directions in respect of a medicinal product of a description¹⁰ or class in relation to which he is not an appropriate practitioner¹¹;
- 158 (3) any person who contravenes any of the provisions of the Medicines Act 1968 as to the sale or supply of medicinal products not on a general sale list¹², the sale or supply of prescription only medicines¹³, the adulteration¹⁴ of the nature or quality of medicinal products¹⁵ or the compliance of such products with specified standards¹⁶, or of regulations as to the restricted sale, supply and administration of medicinal products¹⁷ or of an order¹⁸ as to dealings with such products of specified descriptions¹⁹;
- 159 (4) where a medicinal product is sold, supplied or imported²⁰ in contravention of an order²¹ prohibiting it, any person who, otherwise than for the purpose of performing or exercising a duty or power under the Act or any other enactment²², is in possession of the product knowing or having reasonable cause to suspect that it was sold, supplied or imported in contravention of the order²³;
- 160 (5) any person who contravenes any of the provisions relating to the sale or supply of medicinal products on a general sale list²⁴ or the sale of medicinal products from automatic machines²⁵, or the provisions of an order²⁶ prohibiting certain sales from such machines²⁷;
- 161 (6) any person who contravenes any of the provisions relating to the possession, sale or supply of medicinal products in misleadingly marked containers²⁸, the possession, sale or supply of medicinal products with misleading leaflets²⁹, or equivalent provisions³⁰ relating to medicated animal feeding stuffs³¹.

Any person guilty of such an offence is liable to a penalty³².

1 For the meaning of 'person' see PARA 21 note 7 ante. As to offences by bodies corporate see PARA 181 post.

2 These provisions are subject to the defences provided by the Medicines Act 1968 ss 121, 122 (see PARAS 179-180 post): ss 67(1), 91(1).

3 As to the meaning of 'administer' see PARA 7 note 2 ante.

4 For the meaning of 'medicinal product' see PARA 7 ante.

5 For the meaning of 'contravention' see PARA 6 note 21 ante.

6 Ie under the Medicines Act 1968 s 58 (as amended) by virtue of s 58(4A) (as added): see PARA 140 ante.

7 Ibid s 67(1A) (s 67(1A), (1B) added by the Health and Social Care Act 2001 s 63(1), (7)(a)).

8 Ie by virtue of provision made under the Medicines Act 1968 s 58(1): see PARA 140 ante.

- 9 Ibid s 67(1B)(a) (as added: see note 7 supra).
- 10 As to the description of medicinal products see PARA 7 note 33 ante.
- 11 Medicines Act 1968 s 67(1B)(b) (as added: see note 7 supra).
- 12 See ibid s 52; and PARA 134 ante. For the meaning of 'medicinal products on a general sale list' see PARA 133 ante.
- 13 See ibid s 58 (as amended); and PARA 140 ante.
- 14 See ibid s 63; and PARA 146 ante.
- 15 See ibid s 64; and PARA 147 ante.
- 16 See ibid s 65 (as amended); and PARA 148 ante.
- 17 Ie regulations under ibid s 60 (as amended) or s 61: see PARAS 143-144 ante.
- 18 Ie an order under ibid s 62 (as amended): see PARA 48 ante.
- 19 Ibid s 67(2).
- 20 For the meaning of 'import' see PARA 7 note 3 ante. As to the forfeiture of goods improperly imported see PARA 173 ante.
- 21 Ie an order under the Medicines Act 1968 s 62: see PARA 48 ante.
- 22 For the meaning of 'enactment' see PARA 151 note 6 ante.
- 23 Medicines Act 1968 s 67(3).
- 24 See ibid s 53; and PARA 135 ante.
- 25 See ibid s 54(1); and PARA 136 ante.
- 26 Ie an order under ibid s 54(2): see PARA 136 ante.
- 27 Ibid s 67(5).
- 28 See ibid s 85(5); and PARA 152 ante. For the meaning of 'container' see PARA 152 note 4 ante.
- 29 See ibid s 86(3); and PARA 153 ante. As to the meaning of 'leaflet' see PARA 153 note 5 ante.
- 30 See ibid s 90(2) (repealed).
- 31 Ibid s 91(1). For the meaning of 'animal feeding stuffs' see PARA 7 note 2 ante.
- 32 Any person guilty of an offence under heads (1)-(4) or head (6) in the text is liable on summary conviction to a fine not exceeding the prescribed sum (ibid ss 67(4)(a), 91(1)(a) (s 67(4) amended by the Health and Social Care Act 2001 s 63(1), (7)(b); and the Medicines Act 1968 ss 67(4)(a), 91(1)(a) both amended by virtue of the Magistrates' Courts Act 1980 s 32(2))), or on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both (Medicines Act 1968 ss 67(4)(b), 91(1)(b)); and any person guilty of an offence under head (5) in the text is liable on summary conviction to a fine not exceeding level 3 on the standard scale (s 67(5) (amended by virtue of the Criminal Justice Act 1982 ss 37, 38, 46)). As to the prescribed sum see PARA 32 note 3 ante. As to the standard scale see PARA 6 note 22 ante.

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179. Contravention due to another's default.

Where a contravention¹ by any person² of certain provisions of the Medicines Act 1968³ constitutes an offence under the Act⁴ and is due to an act or default of another person, then, whether proceedings are taken against the first-mentioned person or not, that other person may be charged with and convicted of that offence and is liable on conviction to the same punishment as might have been imposed on the first-mentioned person if he had been convicted of the offence⁵.

Where a person charged with an offence under the Act in respect of a contravention of any of those provisions proves⁶ to the satisfaction of the court that he exercised all due diligence to secure that the provision in question would not be contravened⁷, and that contravention was due to the act or default of another person⁸, the first-mentioned person, if he has given the required notice or obtained the leave of the court⁹, must be acquitted of the offence¹⁰.

1 For the meaning of 'contravention' see PARA 6 note 21 ante.

2 For the meaning of 'person' see PARA 21 note 7 ante.

3 I.e. the Medicines Act 1968 ss 63-65 (s 65 as amended) (see PARAS 146-148 ante), ss 85-89 (s 86 as amended) (see PARAS 152-156 ante), s 90 (repealed), ss 93-96 (all as amended) (see PARAS 158-164 ante), and the provisions of any regulations made under any of those provisions: s 121(4).

4 For the meaning of 's under the Medicines Act 1968' see PARA 170 note 20 ante.

5 Medicines Act 1968 s 121(1).

6 As to the standard of proof on the accused see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(3) (2006 Reissue) PARA 1372.

7 Medicines Act 1968 s 121(2)(a).

8 Ibid s 121(2)(b).

9 A person is not entitled, without the leave of the court, to rely on this defence unless, not later than seven clear days before the date of the hearing, he has served on the prosecutor written notice giving such information, identifying or assisting in the identification of the other person in question, as was then in his possession: ibid s 121(3). For the meaning of 'written' see PARA 21 note 4 ante. As to the service of notices see PARA 37 note 8 ante.

10 Ibid s 121(2).

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180. Warranty as a defence.

In any proceedings for an offence under the Medicines Act 1968¹ in respect of a contravention² of certain provisions³, it is a defence for the defendant to prove⁴: (1) that he purchased the substance⁵ or article to which the contravention relates in the United Kingdom⁶ as being a substance or article which could be lawfully sold, supplied or offered or exposed for sale, or could be lawfully sold, supplied or offered or exposed for sale under the name or description or for the purpose under or for which he sold, supplied or offered or exposed it for sale, and with a written warranty⁷ to that effect⁸; (2) that at the time of the commission of the alleged offence he had no reason to believe that it was otherwise⁹; and (3) that the substance or article was then in the same state as when he purchased it¹⁰.

A defendant may not rely on this defence unless, not later than three clear days before the date of the hearing, he has sent to the prosecutor a copy of the warranty with a notice¹¹ stating that he intends to rely on it and specifying the name and address of the person¹² from whom he received it, and has also sent a like notice to that person¹³. The person by whom the warranty is alleged to have been given is entitled to appear at the hearing and give evidence¹⁴.

If a defendant in any such proceedings for an offence wilfully applies to any substance or article a warranty given in relation to a different substance or article¹⁵, or a certificate of analysis¹⁶ which relates to a sample of a different substance or article¹⁷, he is guilty of an offence¹⁸. A person who, in respect of any substance or article sold by him in respect of which a warranty might be pleaded¹⁹, gives to the purchaser a false warranty in writing is guilty of an offence unless he proves that when he gave the warranty he had reason to believe that the statement or description contained in it was accurate²⁰. Any person guilty of either such offence is liable to a penalty²¹.

1 For the meaning of 'offence under the Medicines Act 1968' see PARA 170 note 20 ante.

2 For the meaning of 'contravention' see PARA 6 note 21 ante.

3 I.e. the Medicines Act 1968 ss 63(b), 64, 65 (s 65 as amended) (see PARAS 146-148 ante), ss 85-88 (s 86 as amended) (see PARAS 152-155 ante), and s 90 (repealed), and the provisions of any regulations made under any of those provisions: s 122(1), (2).

4 As to the standard of proof see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(3) (2006 Reissue) PARA 1372.

5 For the meaning of 'substance' see PARA 7 note 1 ante.

6 For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

7 A name or description entered in an invoice is deemed to be a written warranty that the article or substance to which the name or description applies can be sold, supplied, or offered or exposed for sale under that name or description by any person without contravening the provisions mentioned in note 3 supra: Medicines Act 1968 s 122(6). For the meaning of 'written' see PARA 21 note 4 ante.

8 Ibid s 122(1)(a).

9 Ibid s 122(1)(b).

10 Ibid s 122(1)(c). Where the defendant is an employee of the person who purchased the substance or article under the warranty, he is entitled to rely upon s 122 in the same way as his employer would have been entitled to do if he had been the defendant: s 122(4).

- 11 As to the service of notices see PARA 37 note 8 ante.
- 12 For the meaning of 'person' see PARA 21 note 7 ante.
- 13 Medicines Act 1968 s 122(3).
- 14 Ibid s 122(5). The court may, if it thinks fit, adjourn the hearing to enable him to do so: s 122(5).
- 15 Ibid s 123(1)(a).
- 16 Ie a certificate given under ibid s 115 or Sch 3 para 19: see PARA 171 ante.
- 17 Ibid s 123(1)(b).
- 18 Ibid s 123(1).
- 19 Ie under ibid s 122.
- 20 Ibid s 123(2). Where in any such proceedings as are mentioned in s 122(1) (see the text and notes 1-10 supra) the defendant successfully relies on a warranty given to him or to his employer, proceedings for an offence under s 123(2) in respect of the warranty may, at the prosecutor's option, be taken either before a court having jurisdiction in the place where a sample of the substance or article in question was procured or before a court having jurisdiction in the place where the warranty was given: s 123(3).
- 21 Such a person is liable on summary conviction to a fine not exceeding the prescribed sum (ibid s 123(4)(a) (amended by virtue of the Magistrates' Courts Act 1980 s 32(2))), or on conviction on indictment to a fine or to imprisonment for a term not exceeding two years or to both (Medicines Act 1968 s 123(4)(b)). As to the prescribed sum see PARA 32 note 3 ante.

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181. Offences by bodies corporate.

Where an offence under the Medicines Act 1968¹ committed by a body corporate² is proved to have been committed with the consent and connivance of, or to be attributable to any neglect on the part of, any director³, manager, secretary or other similar officer⁴ of the body corporate, or any person who was purporting to act in such capacity, he as well as the body corporate is liable to be proceeded against and punished accordingly⁵.

1 For the meaning of 'offence under the Medicines Act 1968' see PARA 170 note 20 ante.

2 As to bodies corporate see COMPANIES; CORPORATIONS.

3 'Director', in relation to a body corporate whose affairs are managed by its members and which was established by or under any enactment for the purpose of carrying on under national ownership any industry or part of an industry or undertaking, means a member of that body corporate: Medicines Act 1968 s 124(3). For the meaning of 'enactment' see PARA 151 note 6 ante.

4 In relation to a body corporate carrying on a retail pharmacy business as mentioned in *ibid* s 71(1) (see MEDICAL PROFESSIONS VOL 30(1) (Reissue) PARA 912), s 124(1) has effect in relation to the superintendent, or the pharmacist at any premises where the business is carried on who acts under the directions of the superintendent, as if he were such an officer of the body corporate as is mentioned in s 124(1): s 124(2). For the meaning of 'pharmacist' see PARA 46 note 10 ante.

5 *Ibid* s 124(1).

UPDATE

181 Offences by bodies corporate

NOTE 4--1968 Act s 124(2) amended: Health Act 2006 s 28(2) (in force 1 October 2009: SI 2008/2714).

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182. Disqualification on conviction.

Where in proceedings brought by an enforcement authority¹ a person² is convicted of an offence³ in respect of any premises used for carrying on a retail pharmacy business⁴, then, on the application of that authority, the court by or before which he was convicted may, if it thinks it expedient to do so having regard to the gravity of the offence⁵ or the unsatisfactory nature of the premises⁶ or any previous convictions for such offences⁷, make an order disqualifying him from using those premises for the purposes of such a business for such period, not exceeding two years, as may be specified in the order⁸. If while such an order is in force the premises are used for the purposes of a retail pharmacy business carried on by that person, he is guilty of an offence⁹. At any time after the end of the period of six months¹⁰ from the date on which such an order comes into force, the person to whom it relates may apply to the court by which it was made to revoke the order or to vary it by reducing the period of disqualification¹¹. If the application is refused, no further application may be entertained if made within three months from date of the refusal¹².

1 For the meaning of 'enforcement authority' see PARA 168 note 2 ante.

2 For the meaning of 'person' see PARA 21 note 7 ante.

3 Is an offence under the Medicines Act 1968 s 67(6): see PARA 6 ante.

4 For the meaning of 'retail pharmacy business' see PARA 51 note 3 ante.

5 Medicines Act 1968 s 68(2)(a).

6 Ibid s 68(2)(b).

7 Ibid s 68(2)(c).

8 Ibid s 68(1). No such order may be made unless the authority has given the person against whom it is sought not less than 14 days' written notice of its intention to apply for the order: s 68(3). For the meaning of 'written' see PARA 21 note 4 ante. As to the service of notices see PARA 37 note 8 ante.

9 Ibid s 68(4) (amended by virtue of the Criminal Justice Act 1982 ss 38, 46). Such a person is liable on summary conviction to a fine not exceeding level 5 on the standard scale: see the Medicines Act 1968 s 68(4) (as so amended). As to the standard scale see PARA 6 note 22 ante.

10 For the meaning of 'month' see PARA 22 note 15 ante.

11 Medicines Act 1968 s 68(5). The court may revoke or vary the order if it thinks it proper to do so having regard to all the circumstances including the applicant's conduct and any improvement in the state of the premises (s 68(6)), and may order the applicant to pay the whole or any part of the costs of the application (s 68(7)).

12 Ibid s 68(6).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(11) ENFORCEMENT AND OFFENCES/(ii) Offences and Proceedings/183. Prosecutions.

183. Prosecutions.

Neither the Pharmaceutical Society¹ nor any of certain bodies² may institute proceedings in respect of a contravention³ of any provisions which it has a power or duty to enforce⁴ unless it has given to the appropriate minister⁵ not less than 28 days' notice⁶ of its intention to institute proceedings together with a summary of the facts upon which the charges are founded⁷.

A magistrates' court may try an information for an offence under the Medicines Act 1968⁸ if the information was laid at any time within 12 months⁹ from the commission of the offence¹⁰.

1 For the meaning of 'Pharmaceutical Society' see PARA 2 note 9 ante.

2 I.e. the bodies specified in the Medicines Act 1968 s 108(2), (8) (as amended) (see PARA 168 ante).

3 For the meaning of 'contravention' see PARA 6 note 21 ante.

4 I.e. provisions which by virtue of the Medicines Act 1968 s 108(2), (8) (as amended), the society or body has a power or duty to enforce: see PARA 168 ante.

5 'The appropriate minister' means the minister who in accordance with *ibid* s 108 (as amended) (see PARA 168 ante), has a concurrent duty to enforce the provision: s 125(5).

6 As to the service of notices see PARA 37 note 8 ante.

7 Medicines Act 1968 s 125(4). A certificate of the appropriate minister is conclusive evidence that these provisions have been complied with: s 125(7). Any document purporting to be such a certificate and to be signed by or on behalf of the minister is presumed to be such a certificate unless the contrary is proved: s 125(7).

8 For the meaning of 'offence under the Medicines Act 1968' see PARA 170 note 20 ante.

9 For the meaning of 'month' see PARA 22 note 15 ante.

10 Medicines Act 1968 s 125(1). This is so notwithstanding the provisions of the Magistrates' Courts Act 1980 s 127(1) (see MAGISTRATES vol 29(2) (Reissue) PARA 589): Medicines Act 1968 s 125(1) (amended by the Magistrates' Courts Act 1980 s 154, Sch 7 para 77).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(11) ENFORCEMENT AND OFFENCES/(ii) Offences and Proceedings/184. Presumptions.

184. Presumptions.

Certain presumptions arise for the purposes of any proceedings under the Medicines Act 1968 for an offence consisting of: (1) offering any animal feeding stuff for sale without a licence or certificate¹; or (2) offering a medicinal product² for sale by retail³ in contravention⁴ of the provisions⁵ as to the sale of products on a general sale list⁶ or of products not on such a sale list⁷; or (3) offering⁸ an adulterated medicinal product for sale⁹. Where it is proved in any such proceedings that the animal feeding stuff or medicinal product in question was found on a vehicle from which animal feeding stuffs or medicinal products are sold, it must be presumed, unless the contrary is proved¹⁰, that the person in charge of the vehicle¹¹ offered that animal feeding stuff or medicinal product for sale and, in the case of the sale list provisions¹², that he offered it for sale by retail¹³.

For the purposes of any proceedings for an offence consisting of a contravention of certain provisions¹⁴ so far as they relate to a person's having any medicinal product or animal feeding stuff in his possession for the purpose of sale or supply, where it is proved that the product or feeding stuff was found on premises at which the person charged carries on a business¹⁵ consisting of or including the sale or supply of medicinal products or of animal feeding stuffs in which medicinal products have been incorporated¹⁶, it must be presumed, unless the contrary is proved, that he had that medicinal product or animal feeding stuff in his possession for the purpose of sale or supply¹⁷.

For the purposes of any proceedings for an offence consisting of a contravention of requirements as to leaflets imposed by regulations or of having possession of or supplying a false or misleading leaflet¹⁸ where it is proved that the leaflet in question was found on premises at which the person charged with the offence carries on a business consisting of or including the sale or supply of medicinal products or of animal feeding stuffs in which medicinal products have been incorporated, it must be presumed, unless the contrary is proved, that he had the leaflet in his possession for the purpose of supplying it with a medicinal product¹⁹ or, as the case may be, with the animal feeding stuff²⁰.

1 Medicines Act 1968 s 126(1)(a) (amended by the Animal Health and Welfare Act 1984 s 16 (1), Sch 1 para 3). The offence referred to in the text is that under the Medicines Act 1968 s 40 (repealed). For the meaning of 'animal feeding stuffs' see PARA 7 note 2 ante.

2 For the meaning of 'medicinal product' see PARA 7 ante.

3 As to references to retail sale and selling by retail see PARA 7 note 12 ante.

4 For the meaning of 'contravention' see PARA 6 note 21 ante.

5 I.e. the Medicines Act 1968 s 52 or s 53: see PARAS 134-135 ante.

6 For the meaning of 'medicinal product on a general sale list' see PARA 133 ante.

7 Medicines Act 1968 s 126(1)(b).

8 I.e. in contravention of *ibid* s 63(b): see PARA 146 ante.

9 *Ibid* s 126(1)(c).

10 As to the standard of proof see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(3) (2006 Reissue) PARA 1372.

11 In general, a person who takes a motor vehicle on a road remains in charge of it until he puts it into the charge of some other person: *Haines v Roberts* [1953] 1 All ER 344, [1953] 1 WLR 309, DC.

12 Ie a case falling within head (2) in the text.

13 Medicines Act 1968 s 126(1).

14 Ie ibid s 63(b) (see PARA 146 ante), s 85(3), (5) (see PARA 152 ante), ss 87(2), 88(3) (see PARAS 154-155 ante), any of those provisions as applied by s 90(1), and s 90(2) except in so far as it relates to leaflets: s 126(3). As to the meaning of 'leaflet' see PARA 153 note 5 ante.

15 As to the meaning of 'business' see PARA 7 note 11 ante.

16 As to references to the incorporation of medicinal products in an animal feeding stuff see PARA 173 note 4 ante.

17 Medicines Act 1968 s 126(2).

18 Ie an offence under ibid s 86(2) or s 86(3) (see PARA 153 ante), or so much of s 90(2) as relates to leaflets.

19 Ibid s 126(4)(a).

20 Ibid s 126(4)(b).

UPDATE

184 Presumptions

NOTES--Certain functions under provisions mentioned in this paragraph are 'relevant functions' for the purposes of the Regulatory Enforcement and Sanctions Act 2008 s 4, Sch 3, see LOCAL GOVERNMENT vol 69 (2009) PARA 733.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/ (12) BLOOD SAFETY AND QUALITY/(i) In general/185. Scope of regulation.

(12) BLOOD SAFETY AND QUALITY

(i) In general

185. Scope of regulation.

The requirements relating to blood safety and quality¹ apply to the collection and testing of blood² and blood components³, whatever their intended purpose, and to their processing, storage, and distribution⁴ when they are intended to be used for transfusion⁵. The requirements do not apply to blood stem cells⁶.

The Secretary of State⁷ is designated⁸ as the competent authority⁹.

1 Ie the requirements of the Blood Safety and Quality Regulations 2005, SI 2005/50 (as amended).

2 'Blood' means whole human blood collected from a donor and processed either for transfusion or for further manufacturing: *ibid* reg 1(3).

3 'Blood component' means a therapeutic constituent of human blood (red cells, white cells, platelets and plasma) that can be prepared by various methods: *ibid* reg 1(3).

4 'Distribution' means the act of delivery of blood and blood components to other blood establishments, hospital blood banks and manufacturers of blood products, other than the issuing of blood or blood components for transfusion: *ibid* reg 1(3). For the meaning of 'blood establishment' see PARA 189 note 4 post. For the meaning of 'hospital blood bank' see PARA 194 note 1 post. 'Blood product' means any therapeutic product derived from human blood or plasma: reg 1(3).

5 *Ibid* reg 2(2). The Blood Safety and Quality Regulations 2005, SI 2005/50 (as amended) apply without prejudice to the Medical Devices Regulations 2002, SI 2002/618 (as amended): Blood Safety and Quality Regulations 2005, SI 2005/50, reg 2(3). As to the Medical Devices Regulations 2002, SI 2002/618 (as amended) see PARA 231 et seq post. As to the NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) which has functions with regard to blood and blood components in the national health service see HEALTH SERVICES vol 54 (2008) PARA 147.

6 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 2(4).

7 As to the Secretary of State see PARA 3 note 3 ante.

8 Ie for the purpose of EC Parliament and Council Directive 2002/98 (OJ L033, 8.2.2003, p 30) setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components.

9 Blood Safety and Quality Regulations 2005, SI 2005/50, regs 1(3), 2(1). As to the establishment of the medicines and healthcare products regulatory agency trading fund in connection with certain operations of the Department of Health in relation to blood safety and quality see the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003, SI 2003/1076 (amended by SI 2005/2061). As to government trading funds generally see CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARA 743 et seq.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/ (12) BLOOD SAFETY AND QUALITY/(i) In general/186. Import of blood and blood components.

186. Import of blood and blood components.

No person¹ may import into the United Kingdom² any blood³ or blood components⁴, including blood or blood components intended for use as a starting material or raw material in the manufacture of medicinal products, from a country or territory outside the European Community which does not meet the specified standards of quality and safety⁵.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

3 For the meaning of 'blood' see PARA 185 note 2 ante.

4 For the meaning of 'blood component' see PARA 185 note 3 ante.

5 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 13. The specified standards of quality and safety are standards equivalent to those laid down in Schedule Pt 5: reg 13. It is an offence to contravene reg 13: see reg 18(1)(d); and PARA 201 post.

UPDATE

186 Import of blood and blood components

TEXT AND NOTES--Additionally, such blood or blood components imported from outside the European Community must have been prepared in accordance with a standard equivalent to Community standards and requirements set out in EC Commission Directive 2005/62 Annex: SI 2005/50 reg 13 (substituted by SI 2006/2013).

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187. Specific epidemiological situations.

Where the Secretary of State¹ is aware of a specific epidemiological situation, such as an outbreak of a disease, which may affect the safety of blood² donations, and as a result of which he considers that specific deferral³ criteria for the collection of blood donations should be adopted, he must notify blood establishments⁴ that those criteria must be adopted⁵, and notify the European Commission⁶ of the epidemiological situation⁷ and the additional deferral criteria which blood establishments are required⁸ to adopt in relation to it⁹.

A blood establishment must adopt and comply with any criteria for additional tests notified¹⁰ to it by the Secretary of State¹¹.

1 As to the Secretary of State see PARA 3 note 3 ante.

2 For the meaning of 'blood' see PARA 185 note 2 ante.

3 'Deferral' means suspension of the eligibility of an individual to donate blood or blood components, such suspension being either permanent or temporary: Blood Safety and Quality Regulations 2005, SI 2005/50, reg 1(3). For the meaning of 'blood component' see PARA 185 note 3 ante.

4 For the meaning of 'blood establishment' see PARA 189 note 4 post.

5 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 23(1)(a).

6 See *ibid* reg 1(3).

7 *Ibid* reg 23(1)(b)(i).

8 *Ie* pursuant to *ibid* reg 23(1)(a): see the text to notes 1-5 *supra*.

9 *Ibid* reg 23(1)(b)(ii).

10 *Ie* pursuant to *ibid* reg 23(1): see the text and notes 1-9 *supra*.

11 *Ibid* reg 23(2). It is an offence to contravene this provision: see reg 18(1)(e); and PARA 201 post.

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188. Fees.

Fees are payable by blood establishments¹ to the Secretary of State² in relation to authorisation³, where the Secretary of State carries out an inspection⁴ at a site⁵ of a blood establishment⁶, and in respect of the assessment by the Secretary of State of serious adverse events and serious adverse reactions notified by such establishments⁷. Fees are payable by the person responsible for management of the hospital blood bank⁸ where the Secretary of State carries out an inspection of a hospital blood bank⁹, in respect of each year in which a hospital blood bank has operated¹⁰, and in respect of the assessment by the Secretary of State of serious adverse events and serious adverse reactions notified by such persons¹¹. Where the Secretary of State carries out an inspection of a contract laboratory¹², he may charge the person having control of that laboratory a fee¹³.

The Secretary of State may in exceptional circumstances, where it appears to him to be in the interests of safety or otherwise appropriate to do so, waive any fee or reduce any fee or part of a fee otherwise payable¹⁴, or refund the whole or part of any fee paid¹⁵. All unpaid sums due by way of, or on account of, any fees payable are recoverable as debts due to the Crown¹⁶.

1 For the meaning of 'blood establishment' see PARA 189 note 4 post.

2 See the Blood Safety and Quality Regulations 2005, SI 2005/50, reg 22(1). As to the Secretary of State see PARA 3 note 3 ante.

3 See *ibid* reg 22(2); and PARA 189 post.

4 For the meaning of 'inspection' see PARA 198 note 2 post.

5 For the meaning of 'site' see PARA 189 note 7 post.

6 See the Blood Safety and Quality Regulations 2005, SI 2005/50, reg 22(3); and PARA 198 post.

7 See *ibid* reg 22(2)(bb) (as added); and PARA 192 post.

8 For the meaning of 'person responsible for management of the hospital blood bank' see PARA 194 note 1 post.

9 See the Blood Safety and Quality Regulations 2005, SI 2005/50, reg 22(4), (5); and PARA 198 post. For the meaning of 'hospital blood bank' see PARA 194 note 1 post.

10 See *ibid* reg 22(3A) (as added); and PARA 194 post.

11 See *ibid* reg 22(3B) (as added); and PARA 194 post.

12 'Contract laboratory' means a laboratory carrying out testing of blood or blood components on behalf of, and pursuant to a contractual arrangement with a blood establishment authorised under the Blood Safety and Quality Regulations 2005, SI 2005/50 (as amended) or a person responsible for management of a hospital blood bank: reg 22(6) (definition added by SI 2005/2898). For the meaning of 'blood' see PARA 185 note 2 ante; and for the meaning of 'blood component' see PARA 185 note 3 ante.

13 See the Blood Safety and Quality Regulations 2005, SI 2005/50, reg 22(5A) (reg 22(5A)-(5D) added by SI 2005/2898). As to the amount of such fees see the Blood Safety and Quality Regulations 2005, SI 2005/50, reg 22(5B)-(5D) (as so added).

14 *Ibid* reg 22(9)(a).

15 Ibid reg 22(9)(b).

16 Ibid reg 22(8). As to the enforcement of court orders in respect of debts due to the Crown see CONTEMPT OF COURT vol 9(1) (Reissue) PARA 487; CIVIL PROCEDURE vol 12 (2009) PARA 1239.

UPDATE

188 Fees

TEXT AND NOTES--SI 2005/50 reg 22 amended: SI 2007/604, SI 2008/525, SI 2009/372.

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(ii) Blood Establishments and Blood Banks

189. Authorisation of blood establishments.

No person¹ may carry on any of the specified activities otherwise than in accordance with an authorisation². The specified activities are: (1) the collection and testing of blood or blood components, whatever their intended purpose³; and (2) the processing, storage and distribution of blood and blood components when they are intended to be used for transfusion⁴.

The Secretary of State⁵ may grant an authorisation to a blood establishment to carry out any of the specified activities⁶ following an application for authorisation made to him⁷. An application must include the prescribed information⁸ and be accompanied by the prescribed fee⁹. Where the Secretary of State grants an application for authorisation, he must give notice in writing to the blood establishment specifying the activities which the blood establishment may undertake at each site in respect of which authorisation is granted¹⁰, and the conditions which apply to the undertaking of those activities¹¹. The Secretary of State may at any time remove or vary any of the conditions subject to which the authorisation is granted, or may impose additional conditions¹². A blood establishment may not make any substantial change in the activities which it undertakes¹³ without the prior written approval of the Secretary of State¹⁴.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 3(1). This restriction does not apply to:

75 (1) the storage and distribution of, and the performance of compatibility tests on, blood and blood components exclusively for use within hospital facilities, including transfusion activities where such activities are performed by a hospital blood bank (reg 3(3)(a)); or

76 (2) any person carrying out any of the specified activities, where that person carries out that activity on behalf of, and pursuant to a contractual arrangement with:

16. (a) a blood establishment which is authorised under these provisions to carry out the activity in question (reg 3(3)(b)(i)); or

16

17. (b) a person responsible for management of a hospital blood bank (reg 3(3)(b)(ii)).

17

For the meaning of 'distribution' see PARA 185 note 4 ante; for the meaning of 'blood' see PARA 185 note 2 ante and for the meaning of 'blood component' see PARA 185 note 3 ante. For the meanings of 'hospital', 'hospital blood bank' and 'person responsible for management of a hospital blood bank' see PARA 194 note 1 post. As to offences relating to the contravention of reg 3(1) see PARA 201 post.

3 Ibid reg 3(2)(a).

4 Ibid reg 3(2)(b). 'Blood establishment' means any person who carries out any of the activities specified in reg 3(2) (see heads (1), (2) in the text) which require an authorisation by virtue of that regulation: reg 1(3) (definition amended by SI 2005/2898).

5 As to the Secretary of State see PARA 3 note 3 ante.

6 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 4(1).

7 Ibid reg 4(2). The Secretary of State may grant or refuse any application for authorisation made to him (reg 4(5)(a)); and he may grant such an application in respect of particular sites or activities only (reg 4(5)(b)(i)), and subject to conditions (reg 4(5)(b)(ii)). 'Site', in relation to a blood establishment, means any premises at

which the blood establishment carries out any of the activities listed in reg 3(2) (see heads (1), (2) in the text), but does not include any premises not owned or managed by the blood establishment at which blood is collected, or any mobile blood collection unit: reg 1(3). As to objections to the refusal of authorisation or the imposition of conditions see PARA 196 post.

8 Ibid reg 4(3)(a). As to the prescribed information see reg 4(4) (amended by SI 2005/1098).

9 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 4(3)(b). The fee payable in respect of an application is the sum of £2,444 (reg 22(2)(a)) and it is payable at the time the application is made (reg 22(7)(i)). As to fees generally see PARA 188 ante.

10 Ibid reg 4(6)(a).

11 Ibid reg 4(6)(b). An annual fee of the sum of £304 is payable in connection with the holding of an authorisation: reg 22(2)(c). As to when such fee is payable see the Blood Safety and Quality Regulations 2005, SI 2005/50, reg 22(7)(ii), (7A) (reg 22(7) amended, (7A) added, by SI 2005/2898).

12 Blood Safety and Quality Regulations 2005, SI 2005/50 reg 4(7). Where the Secretary of State removes or varies any condition or imposes any additional condition, he must serve a notice on the blood establishment in question which must: (1) give details of the conditions which he proposes to remove, or of the variation which he proposes to make to any existing conditions, or of any additional condition which he proposes to impose (reg 4(8)(a)); (2) give the reasons for his decision (reg 4(8)(b)); and (3) specify the date, which must be not less than 14 days from the date on which the notice is served, from which the removal or variation of any condition, or the imposition of any additional condition, applies (reg 4(8)(c)). As to objections to suspensions or revocations, and as to objections to any such notice, see PARA 196 post.

13 A substantial change in a blood establishment's activities is any change: (1) to the sites from which the blood establishment operates or to the activities to be carried out at each site (ibid reg 4(11)(a)); (2) which would result in breach of the Blood Safety and Quality Regulations 2005, SI 2005/50 (as amended) or of any condition to an authorisation specified by the Secretary of State (reg 4(11)(b)); or (3) to the quality system which is likely to have a substantial impact on the conduct of, or might compromise the safety of, any of the activities which the blood establishment has been authorised to undertake (reg 4(11)(c)).

14 Ibid reg 4(9). Any application for approval to make a substantial change in its activities must be made in writing to the Secretary of State, and be accompanied by the prescribed fee: reg 4(10). The fee payable is the sum of £400 (reg 22(2)(b)) and it is payable at the time the application is made (reg 22(7)(i)). It is an offence to contravene reg 4(9): see PARA 201 post.

UPDATE

189 Authorisation of blood establishments

NOTE 2--Head (1) omit 'or'; head (2) for 'and pursuant', substitute 'or pursuant'; at the end of head (2)(b) insert 'and': SI 2005/50 reg 3(3)(a), (b) (amended by SI 2006/2013). Head (3) the import of blood and blood components from outside the European Community when undertaken by (a) a manufacturer; or (b) a person acting on behalf of and pursuant to a contractual arrangement with a manufacturer, for the purposes of manufacturing a medicinal product within the meaning of the Medicines Act 1968 or the Medical Devices Regulations 2002, SI 2002/618 (amended by SI 2007/400): SI 2005/50 reg 3(3)(c) (added by SI 2006/2013).

TEXT AND NOTE 4--Also head (3) the import of blood or blood components from outside the European Community: SI 2005/50 reg 3(2)(c) (added by SI 2006/2013).

NOTE 9--Fee now £3,044: SI 2005/50 reg 22(2)(a) (amended by SI 2009/372).

NOTE 11--SI 2008/525 reg 22(2)(c) amended: SI 2008/525.

NOTE 14--Fee now £513: SI 2005/50 reg 22(2)(b) (amended by SI 2009/372).

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190. Suspension or revocation of authorisation.

The Secretary of State¹ may suspend or revoke the authorisation of a blood establishment² on one or more of the following grounds: (1) that the blood establishment has failed, in any material respect, to comply with the appropriate requirements³; (2) that the collection, testing, processing, storage or distribution⁴ of blood or blood components⁵ by the establishment cannot be carried out safely⁶; (3) that any blood or blood components cannot be supplied to hospital blood banks⁷ in such a state that they could be safely administered for transfusion⁸; or (4) that the information given⁹ by the blood establishment in its application for authorisation was false or incomplete in any material respect¹⁰. Before suspending or revoking the authorisation of a blood establishment, the Secretary of State must serve a notice on the blood establishment stating that he intends to suspend or revoke its authorisation with effect from the date specified in the notice¹¹; except that, where the Secretary of State considers that it is necessary in the interests of safety, he may, by a notice served on a blood establishment, suspend or revoke its authorisation with immediate effect¹².

However, where the blood establishment is in contravention of head (1) or head (4) above¹³ and the Secretary of State considers that the failure in question is not sufficiently serious to warrant suspension or revocation of the authorisation of the blood establishment in the first instance, he may serve a notice on the responsible person of the blood establishment¹⁴ identifying the requirements of which the blood establishment is in breach or, in the case of false and incomplete information, the further information which is required¹⁵, identifying the action which the blood establishment is required to take¹⁶, and giving the timescale within which the blood establishment must take such action¹⁷. If the blood establishment fails to comply with the requirements set out in the notice within the specified timescale, the Secretary of State may, by a notice served on the blood establishment, suspend or revoke the authorisation¹⁸.

Any suspension pursuant to these provisions is for such period as the Secretary of State considers necessary having regard to the reasons for the suspension¹⁹, and may be total, or may be limited to a particular activity or to one or more activities carried out at a particular site²⁰ or sites, or to a particular blood component²¹.

1 As to the Secretary of State see PARA 3 note 3 ante.

2 For the meaning of 'blood establishment' see PARA 189 note 4 ante. As to authorisations see PARA 189 ante.

3 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 5(1)(a). The appropriate requirements are those of the Blood Safety and Quality Regulations 2005, SI 2005/50 (as amended).

4 For the meaning of 'distribution' see PARA 185 note 4 ante.

5 For the meaning of 'blood' see PARA 185 note 2 ante; and for the meaning of 'blood component' see PARA 185 note 3 ante.

6 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 5(1)(b).

7 For the meaning of 'hospital blood bank' see PARA 194 note 1 post.

8 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 5(1)(c).

9 Ie pursuant to ibid reg 4(3): see PARA 189 ante.

10 Ibid reg 5(1)(d).

11 Ibid reg 5(2). Such date must be not less than seven days from the date on which the notice is served: reg 5(2). As to objections to any notice served under reg 5 or to any suspension or revocation of authorisation see PARA 196 post.

12 Ibid reg 5(3). See also note 11 *supra*.

13 Ibid reg 5(4)(a), (b) (amended by SI 2005/1098).

14 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 5(4). For the meaning of 'responsible person' see PARA 191 note 2 post.

15 Ibid reg 5(5)(a).

16 Ibid reg 5(5)(b).

17 Ibid reg 5(5)(c). See also note 11 *supra*.

18 Ibid reg 5(6). Such a suspension or revocation takes effect, in a case where the Secretary of State considers that it is necessary in the interests of safety, immediately (reg 5(7)(a)); or, in all other cases, from a date specified in the notice (reg 5(7)(b)). See also note 11 *supra*.

19 Ibid reg 5(8).

20 For the meaning of 'site' see PARA 189 note 7 *ante*.

21 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 5(9). It is an offence to fail to comply with a notice of suspension or revocation served pursuant to reg 5 (as amended): see reg 18(3); and PARA 201 post.

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191. The responsible person for a blood establishment.

A blood establishment¹ must designate a person² who is responsible for the following tasks: (1) ensuring that every unit of blood or blood component that has been collected or tested for any purpose has been collected and tested in accordance with the specified requirements³; (2) ensuring that every unit of blood or blood components intended for transfusion has been processed, stored and distributed in accordance with those requirements⁴; (3) providing⁵ information to the Secretary of State relating to the authorisation of the blood establishment⁶; and (4) the implementation in the blood establishment of the blood establishment requirements⁷, and the requirements as to labelling of blood and blood components and traceability⁸, and as to disclosure of information⁹. The responsible person may delegate any of these tasks to other persons who are qualified by training and experience to perform them¹⁰.

If the Secretary of State considers that the responsible person does not meet the requirements as to qualification¹¹ or that he is failing to carry out the tasks specified in heads (1) to (4) above adequately or at all, he may serve a notice to that effect on the blood establishment¹². If, within 14 days of receiving such a notice, a blood establishment is not able to demonstrate to the reasonable satisfaction of the Secretary of State that the responsible person does meet those requirements or that he is carrying out those tasks adequately, it must, without delay relieve him of the duties of responsible person in respect of the establishment¹³, appoint a new responsible person in his place¹⁴, and notify the Secretary of State that it has appointed a new responsible person and provide details of the name and qualifications of the person appointed¹⁵.

1 For the meaning of 'blood establishment' see PARA 189 note 4 ante.

2 A blood establishment must not designate a person unless that person has: (1) a diploma, certificate or other evidence of formal qualification in the field of medical or biological sciences awarded on completion of a university course of study (Blood Safety and Quality Regulations 2005, SI 2005/50, reg 6(2)(a)(i)), or a course recognised as an equivalent course by the Secretary of State (reg 6(2)(a)(ii)); and (2) practical post-graduate experience in areas of work relevant to the responsibilities of the responsible person for at least two years, in an establishment (or more than one establishment) authorised in any member state to undertake activities related to the collection or testing (or both) of blood and blood components, or to their preparation, storage and distribution (reg 6(2)(b)). The Secretary of State must from time to time publish details of courses recognised by him for the purpose of reg 6(2)(a)(ii): reg 6(3). 'Responsible person' in relation to a blood establishment means the person who has been designated pursuant to reg 6 as the responsible person for that blood establishment: reg 1(3). As to the Secretary of State see PARA 3 note 3 ante. For the meaning of 'member state' see the European Communities Act 1972 s 1(2), Sch 1 Pt II; and the Interpretation Act 1978 s 5, Sch 1. For the meaning of 'blood' see PARA 185 note 2 ante; and for the meaning of 'blood component' see PARA 185 note 3 ante. For the meaning of 'distribution' see PARA 185 note 4 ante.

3 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 6(1)(a). The specified requirements are those of the Blood Safety and Quality Regulations 2005, SI 2005/50 (as amended).

4 Ibid reg 6(1)(b).

5 Ie for the purpose of ibid reg 4: see PARA 189 ante.

6 Ibid reg 6(1)(c). As to offences relating to the contravention of reg 6 (other than reg 6(3)) see reg 18(2)(b); and PARA 201 post.

7 Ie under ibid reg 7: see PARA 192 post.

8 Ie under ibid reg 8: see PARA 193 post.

9 Ibid reg 6(1)(d). The requirements as to disclosure of information are those under reg 14: see PARA 197 post.

10 Ibid reg 6(4). Blood establishments must notify the Secretary of State of the name of any persons to whom tasks have been delegated by the responsible person, and the specific tasks which have been delegated to such persons: reg 6(5). Where the responsible person or a person to whom tasks have been delegated is permanently or temporarily replaced, the blood establishment must without delay provide the Secretary of State with the name of the replacement, details of his qualifications and the date on which the replacement began his duties: reg 6(6).

11 Ie the requirements of ibid reg 6(2): see note 2 supra.

12 Ibid reg 6(7) (reg 6(7), (8) amended by SI 2005/2898).

13 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 6(8)(a) (as amended: see note 12 supra).

14 Ibid reg 6(8)(b).

15 Ibid reg 6(8)(c).

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192. Blood establishment requirements.

A blood establishment¹ must: (1) ensure that the personnel directly involved in the collection, testing, processing, storage and distribution² of human blood and blood components³ for the blood establishment are qualified to perform those tasks and are provided with timely, relevant and regularly updated training⁴; (2) establish and maintain a quality system for blood establishments based on the principles of good practice⁵; (3) ensure that all testing and processes⁶ of the blood establishment are validated⁷; (4) maintain documentation on operational procedures, guidelines, training and reference manuals and reporting forms so that they are readily available for inspection⁸; (5) notify the Secretary of State⁹ of any serious adverse events¹⁰ related to the collection, testing, processing, storage and distribution of blood and blood components by the blood establishment which may have an influence on their quality and safety¹¹, and any serious adverse reactions¹² observed during or after transfusion which may be attributable to the quality or safety of blood or blood components collected, tested, processed, stored or distributed by the blood establishment¹³; and (6) establish and maintain a procedure, which is accurate, efficient and verifiable, for the withdrawal from distribution of blood or blood components associated with any such notification¹⁴.

In relation to the donation of blood, a blood establishment must: (a) give all prospective donors of blood or blood components the required information¹⁵; (b) obtain the required information¹⁶ from all persons who are willing to provide blood or blood components¹⁷; (c) put and keep in place procedures for the evaluation of donors¹⁸; (d) apply eligibility criteria¹⁹ for all donors of blood and blood components²⁰; (e) maintain records of the results of donor evaluations and report to donors any relevant abnormal findings from the evaluations²¹; (f) ensure that an examination of the donor, including an interview, is carried out before any donation of blood or blood components²², that a qualified health professional²³ is responsible for giving to and gathering from donors the information which is necessary to assess their eligibility to donate²⁴, and that, on the basis of that information, a qualified health professional assesses the eligibility of all donors to donate²⁵; and (g) encourage voluntary and unpaid blood donations with a view to ensuring that blood and blood components are, in so far as possible, provided from such donations, in particular, by disseminating information about blood donation²⁶ and advertising for blood donors²⁷.

A blood establishment must ensure that, in relation to the blood and blood components which it collects, processes, stores or distributes: (i) each donation of blood and blood components, including blood and blood components which are imported into the European Community, is tested in conformity with the basic testing requirements²⁸ for whole blood and apheresis donations²⁹, and any additional tests which may be necessary for specific components, types of donors or epidemiological situations³⁰; (ii) the storage, transport and distribution conditions of blood and blood components comply with the specified requirements³¹; and (iii) quality and safety requirements for blood and blood components meet the specified standards³².

A blood establishment must, in relation to the activities³³ for which it is responsible, maintain records for a minimum period of 15 years³⁴. As soon as practicable after the end of the reporting year³⁵, each blood establishment must provide to the Secretary of State a report specifying the information³⁶ relating to the blood and blood components which it collects, processes, stores or distributes for that year³⁷, and details of the steps it has taken during that year to comply with its obligation³⁸ to encourage donations³⁹.

- 1 For the meaning of 'blood establishment' see PARA 189 note 4 ante.
- 2 For the meaning of 'distribution' see PARA 185 note 4 ante.
- 3 For the meaning of 'blood' see PARA 185 note 2 ante; and for the meaning of 'blood component' see PARA 185 note 3 ante.
- 4 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 7(1)(a). As to offences relating to the contravention of reg 7 see reg 18(1)(b); and PARA 201 post.
- 5 Ibid reg 7(1)(b).
- 6 As to such testing and processes see ibid Schedule Pts 2-5.
- 7 Ibid reg 7(1)(c). 'Validation' means the establishment of documented and objective evidence that the particular requirements for a specific intended use can be consistently fulfilled: reg 1(3).
- 8 Ibid reg 7(1)(d). As to inspection see reg 15; and PARA 198 post.
- 9 As to the Secretary of State see PARA 3 note 3 ante.
- 10 'Serious adverse event' means any untoward occurrence associated with the collection, testing, processing, storage and distribution of blood or blood components that might lead to death or life-threatening, disabling or incapacitating conditions for patients or which results in, or prolongs, hospitalisation or morbidity: Blood Safety and Quality Regulations 2005, SI 2005/50, reg 1(3).
- 11 Ibid reg 7(1)(e)(i).
- 12 'Serious adverse reaction' means an unintended response in a donor or in a patient associated with the collection or transfusion of blood or blood components that is fatal, life-threatening, disabling or incapacitating, or which results in or prolongs hospitalisation or morbidity: ibid reg 1(3).
- 13 Ibid reg 7(1)(e)(ii). In respect of the assessment by the Secretary of State of serious adverse events and serious adverse reactions notified by blood establishments, an annual haemovigilance fee is payable: see reg 22(2)(bb),(2A), (7)(iia) (all added by SI 2005/2898).
- 14 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 7(1)(f).
- 15 Ibid reg 7(2)(a). As to the required information see Schedule Pt 2 Pt A.
- 16 As to the required information see ibid Schedule Pt 2 Pt B.
- 17 Ibid reg 7(2)(b).
- 18 Ibid reg 7(2)(c).
- 19 As to such criteria see ibid Schedule Pt 3.
- 20 Ibid reg 7(2)(d).
- 21 Ibid reg 7(2)(e).
- 22 Ibid reg 7(2)(f)(i).
- 23 'Qualified health professional' means a doctor, a nurse, or a donor carer: ibid reg 1(3). 'Doctor' means a registered medical practitioner (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 4); and 'nurse' means a registered nurse or registered midwife (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 716 et seq): reg 1(3). 'Donor carer' means a person who has passed both the written and practical examinations of the NHS Blood and Transplant (Gwaed a Thrawsblaniadau'r GIG) (see HEALTH SERVICES vol 54 (2008) PARA 147), the Scottish National Blood Transfusion Service, the Northern Ireland Blood Transfusion Service or the Welsh Blood Service in the care of blood donors and who holds a current certificate of competence, awarded by that body, in the care of blood donors: reg 1(3) (amended by SI 2005/2532).
- 24 Blood Safety and Quality Regulations 2005, SI 2005/50 reg 7(2)(f)(ii).
- 25 Ibid reg 7(2)(f)(iii).
- 26 Ibid reg 7(2)(g)(i).

27 Ibid reg 7(2)(g)(iii).

28 As to such requirements see ibid reg 7(7).

29 Ibid reg 7(3)(a)(i).

30 Ibid reg 7(3)(a)(ii). The Secretary of State may issue guidance as to the additional tests which are necessary in relation to specific components, types of donor or epidemiological situations; and blood establishments must have regard to such guidance: reg 7(8).

31 Ibid reg 7(3)(b). As to the specified requirements see Schedule Pt 4.

32 Ibid reg 7(3)(c). As to the specified standards see Schedule Pt 5.

33 Ie specified in ibid reg 3(2): see PARA 189 ante.

34 Ibid reg 7(4). The records are to be records of the specified information (reg 7(4)(a)) and the conduct of the tests referred to in reg 7(3)(a) (see the text to notes 28-30 supra) (reg 7(4)(b)). The specified information is: the total number of donors who give blood and blood components (reg 7(5)(a)); the total number of donations (reg 7(5)(b)); an updated list of the hospital blood banks which it supplies (reg 7(5)(c)); the total number of whole donations not used (reg 7(5)(d)); the number of each component produced and distributed (reg 7(5)(e)); the incidence and prevalence of transfusion transmissible infectious markers in donors of blood and blood components (reg 7(5)(f)); the number of product recalls (reg 7(5)(g)); the number of serious adverse events and serious reactions reported (reg 7(5)(h)); the information provided to donors by the blood establishment in accordance with reg 7(2)(a) (see the text to note 15 supra) (reg 7(6)(a)); the information obtained from donors by the blood establishment in accordance with reg 7(2)(b) (see the text to notes 16-17 supra) (reg 7(6)(b)); and the information relating to the suitability of blood and plasma donors in accordance with the eligibility criteria specified in Schedule Pt 3 (reg 7(6)(c)). For the meaning of 'hospital blood bank' see PARA 194 note 1 post.

35 'Reporting year' means the period of 12 months ending on 31 March: ibid reg 1(3). For the meaning of 'month' see PARA 22 note 15 ante.

36 Ie the information referred to in ibid reg 7(3): see the text to notes 28-32 supra.

37 Ibid reg 7(9)(a).

38 Ie under ibid reg 7(2)(g): see the text to notes 26-27 supra.

39 Ibid reg 7(9)(b).

UPDATE

192 Blood establishment requirements

NOTE 5--SI 2005/50 reg 7(1)(d) amended: SI 2006/2013.

NOTE 6--See now SI 2005/50 Schedule Pts 2-8 (Pts 6-8 added by SI 2006/2013).

TEXT AND NOTES 9-13--Omit head (5): SI 2005/50 reg 7(1) (reg 7(1)(e) revoked by SI 2006/2013).

NOTE 13--SI 2005/50 reg 22(2A) amended: SI 2008/525, SI 2009/372.

TEXT AND NOTE 14--Also head (7) retain, for a period of at least 15 years, a record of any serious adverse events which may affect the quality or safety of blood and blood components: SI 2005/50 reg 7(1)(g) (added by SI 2006/2013).

TEXT AND NOTES 15-27--SI 2005/50 reg 7(2A)-(2C) added: SI 2009/3307.

NOTE 20--SI 2005/50 reg 7(2)(d) amended: SI 2009/3307.

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193. Labelling of blood and blood components, and traceability.

A blood establishment¹ must ensure that the label on each unit of blood or blood component² supplied by it, or imported by it from outside the European Community, contains the specified information³. A blood establishment must keep such records of that information, and such additional records as are necessary, for the identification of each single blood donation and each single blood unit and its components, including blood and blood components which are imported into the European Community⁴, and to ensure full traceability to the point of delivery to a hospital⁵. Such records must be kept for a period of not less than 30 years⁶.

1 For the meaning of 'blood establishment' see PARA 189 note 4 ante.

2 For the meaning of 'blood' see PARA 185 note 2 ante; and for the meaning of 'blood component' see PARA 185 note 3 ante.

3 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 8(1). As to the specified information see reg 8(1)(a)-(i). As to offences relating to the contravention of reg 8 see reg 18(2)(c); and PARA 201 post.

4 Ibid reg 8(2)(a).

5 Ibid reg 8(2)(b). For the meaning of 'hospital' see PARA 194 note 1 post.

6 Ibid reg 8(2).

UPDATE

193 Labelling of blood and blood components, and traceability

TEXT AND NOTES 4-6--SI 2005/50 reg 8(2) now reg 8(2), (3) (reg 8(2) substituted, reg 8(3)-(6) added by SI 2006/2013; SI 2005/50 reg 8(3) amended by SI 2008/941). Records must be in an appropriate and readable storage medium: SI 2005/50 reg 8(3) (as so added and amended). A blood establishment must ensure that the traceability system in place in the blood establishment enables the tracing of blood and blood components to their location and processing stage: reg 8(4) (as so added). 'Traceability' means the ability to trace each individual unit of blood or blood component from the donor to its final destination, whether this is a recipient, a manufacturer of medical products or disposal, and from its final destination back to the donor: reg 1(3) (definition added by SI 2006/2013). The establishment must have in place a system to uniquely identify each donor, each blood unit collected and each blood component prepared, whatever its intended purpose, and the facilities to which a given unit of blood or blood component has been delivered: SI 2005/50 reg 8(5) (as so added). The establishment must ensure, when it issues a unit of blood or blood components for transfusion, that the facility to which the unit of blood is issued has in place a procedure to verify that each unit of blood issued has been transfused to the intended recipient or, if not transfused, to verify its subsequent disposition: reg 8(6) (as so added). 'Issue' means the provision of blood or blood components by a blood establishment or a hospital bank for transfusion to a recipient: reg 1(3) (definition added by SI 2006/2013).

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194. Hospital blood bank requirements.

The person responsible for the management of a hospital blood bank¹ must: (1) ensure that personnel directly involved in the testing, storage and distribution of human blood and blood components for the hospital blood bank are qualified to perform those tasks and are provided with timely, relevant and regularly updated training²; (2) establish and maintain a quality system for the hospital blood bank which is based on the principles of good practice³; (3) ensure that all processes⁴ which are applicable to activities carried out by the hospital blood bank are validated⁵; (4) maintain documentation on operational procedures, guidelines, training and reference manuals and reporting forms so that they are readily available for inspection⁶; (5) maintain, for not less than 30 years, the data needed to ensure full traceability of blood and blood components, from the point of receipt of the blood or blood component by the hospital blood bank⁷; (6) notify the Secretary of State⁸ of any serious adverse events⁹ related to the testing, storage and distribution of blood and blood components by the hospital blood bank which may have an influence on their quality and safety¹⁰, and any serious adverse reactions¹¹ observed during or after transfusion which may be attributable to the quality or safety of blood or blood components issued for transfusion by the hospital blood bank¹²; (7) establish and maintain a procedure, which is accurate, efficient and verifiable, for the withdrawal from distribution of blood or blood components associated with any such notification¹³; and (8) ensure that the storage, transport and distribution conditions of blood and blood components by the hospital blood bank comply with the specified requirements¹⁴.

On or before the specified date¹⁵, the person responsible for management of a hospital blood bank must submit a report to the Secretary of State, which must include a declaration that the hospital blood bank has in place appropriate systems to ensure compliance with the specified requirements¹⁶, and provide details of the systems which it has in place to ensure such compliance¹⁷.

1 'Person responsible for management of a hospital blood bank' means in the case of a hospital blood bank located in a hospital managed by a health service body, that body; and in the case of an independent hospital, the registered person: Blood Safety and Quality Regulations 2005, SI 2005/50, reg 1(3). 'Hospital blood bank' means any unit within a hospital which stores and distributes, and may perform compatibility tests on, blood and blood components exclusively for use within hospital facilities, including hospital based transfusion activities: reg 1(3). 'Hospital' means a health service hospital or an independent hospital; 'health service hospital' has the same meaning as in the National Health Service Act 1977 s 128 (see HEALTH SERVICES vol 54 (2008) PARA 21); and 'independent hospital' has the same meaning as in the Care Standards Act 2000 s 2 (see CHILDREN AND YOUNG PERSONS vol 5(4) (2008 Reissue) PARA 983): Blood Safety and Quality Regulations 2005, SI 2005/50, reg 1(3). For the meaning of 'blood' see PARA 185 note 2 ante; and for the meaning of 'blood component' see PARA 185 note 3 ante. For the meaning of 'distribution' see PARA 185 note 4 ante. 'Health service body' means a strategic health authority, special health authority, primary care trust or local health board established under the National Health Service Act 1977; a national health service trust established under the National Health Service and Community Care Act 1990; or an NHS foundation trust within the meaning of the Health and Social Care (Community Health and Standards) Act 2003 s 1(1): Blood Safety and Quality Regulations 2005, SI 2005/50, reg 1(3). As to all such bodies see HEALTH SERVICES vol 54 (2008) PARA 75 et seq. 'Registered person' means the person registered as the manager of an independent hospital following an application to be registered as such pursuant to the Care Standards Act 2000 s 12(3) (see SOCIAL SERVICES AND COMMUNITY CARE): Blood Safety and Quality Regulations 2005, SI 2005/50, reg 1(3). For the meaning of 'person' see PARA 21 note 7 ante.

2 Ibid reg 9(1)(a). As to offences relating to the contravention of reg 9 see reg 18(1)(c); and PARA 201 post.

3 Ibid reg 9(1)(b).

- 4 As to such processes see *ibid* Schedule Pt 4.
- 5 *Ibid* reg 9(1)(c). For the meaning of 'validation' see PARA 192 note 7 ante.
- 6 *Ibid* reg 9(1)(d). As to inspection see reg 15; and PARA 198 post.
- 7 *Ibid* reg 9(1)(e).
- 8 As to the Secretary of State see PARA 3 note 3 ante.
- 9 For the meaning of 'serious adverse event' see PARA 192 note 10 ante.
- 10 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 9(1)(f)(i).
- 11 For the meaning of 'serious adverse reaction' see PARA 192 note 12 ante.
- 12 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 9(1)(f)(ii). In respect of the assessment by the Secretary of State of serious adverse events and serious adverse reactions notified by hospital blood banks an annual haemovigilance fee is payable: see reg 22(3B)-(3D), (7)(ia), (iib) (all added by SI 2005/2898).
- 13 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 9(1)(g).
- 14 *Ibid* reg 9(1)(h). As to the specified requirements see Schedule Pt 4.
- 15 The specified date is, in relation to the reporting year ending on 31 March 2006, 31 December 2005; and in relation to each subsequent reporting year, 30 April following the end of that year: *ibid* reg 10(1A) (reg 10(1) amended, (1A) added, by SI 2005/2898). For the meaning of 'reporting year' see PARA 192 note 35 ante.
- 16 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 10(1)(a) (as amended: see note 15 supra). The specified requirements are those of the Blood Safety and Quality Regulations 2005, SI 2005/50 (as amended). The person responsible for management of a hospital blood bank must without delay notify the Secretary of State of any changes to the matters in respect of which evidence has been supplied pursuant to reg 10(1) which might affect compliance with those requirements: reg 10(2). As to offences relating to the contravention of reg 10 see reg 18(2)(d); and PARA 201 post.
- 17 *Ibid* reg 10(1)(b). A fee is payable to the Secretary of State in respect of each reporting year in which a hospital blood bank has operated: see reg 22(3A) (added by SI 2005/2898).

UPDATE

194 Hospital blood bank requirements

NOTE 1--'Health service hospital' now means a hospital owned or managed by a health service body; 'registered person' now means the person registered as a manager of an independent hospital, a care home or an independent clinic following an application to be registered as such pursuant to the Care Standards Act 2000 s 12(3); 'care home' and 'independent clinic' have the same meanings as in s 3: SI 2005/50 reg 1(3) (amended by SI 2006/2013).

NOTE 3--SI 2005/50 reg 9(1)(b) amended: SI 2006/2013.

TEXT AND NOTE 7--Now head (5) maintain in an appropriate and readable storage medium and for a period of not less than 30 years (a) the record of data on traceability by blood establishments and by facilities, insofar as those data are applicable to the activities carried out by the hospital blood bank; and (b) such other data as are needed to endure full traceability of blood and blood components and the unique identification of each unit of blood and each blood component from the point of receipt of the blood or blood components by the hospital blood bank: SI 2005/50 reg 9(1)(e) (substituted by SI 2006/2013). 'Facility' means a hospital, any other facility or service owned or managed by a health service body, a care home, an independent clinic, a manufacturer, or, a biomedical research institute: SI 2005/50 reg 1(3) (definition added by SI 2006/2013).

TEXT AND NOTES 8-12--Now head (6) retain, for a period of at least 15 years, a record of any serious adverse events which may affect the quality or safety of blood and blood components: SI 2005/50 reg 9(1)(f) (substituted by SI 2008/941).

NOTE 12--After 'hospital blood banks' read 'or facilities': SI 2005/50 reg 22(3B) (amended by SI 2006/2013). SI 2005/50 reg 22(3C) amended: SI 2008/525, SI 2009/372. See also SI 2005/50 reg 22(3E) (added by SI 2006/2013).

TEXT AND NOTE 14--Also heads (9) ensure that the traceability system in place in the hospital blood bank enables the tracing of blood components to their final destination; (10) where it delivers blood or blood components for a transfusion at another facility, have in place a system to uniquely identify the facility to which a given unit of blood or blood component has been delivered: SI 2005/50 reg 9(1)(i), (j) (added by SI 2006/2013).

NOTE 14--A person responsible for management of a hospital blood bank must ensure that when a hospital blood bank issues a unit of blood for transfusion, that it has in place a procedure to verify that each unit of blood issued has been transfused to the intended recipient, or if not transfused, to verify its subsequent disposition: SI 2005/50 reg 9(2) (added by SI 2006/2013).

NOTE 17--SI 2005/50 reg 22(3A) amended: SI 2008/525, SI 2009/372.

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195. Notices relating to hospital blood banks.

If the Secretary of State¹ is of the opinion that the person responsible for management of a hospital blood bank² has failed, in any material respect, to comply with the specified requirements³, or that the testing, storage or distribution⁴ of blood or blood components⁵ by the hospital blood bank is such that any blood or blood components cannot be safely administered for transfusion⁶, or that the information given⁷ by the person responsible for management of a hospital blood bank was false or incomplete in any material respect⁸, he may serve a notice on the person responsible for management of the hospital blood bank requiring the hospital to cease to conduct any of the activities specified in the notice, or to refrain from administering to patients any blood or blood components specified in the notice, until certain requirements are met⁹. The requirements are, as may be applicable in each case, that: (1) the person responsible for management of the hospital blood bank is no longer in breach of the specified requirements¹⁰; (2) the hospital blood bank is able to show that the activity or product referred to in the notice¹¹ may be safely carried out or, as the case may be, administered¹²; or (3) that all necessary information has been supplied to the Secretary of State¹³.

Any notice served by the Secretary of State must specify the date from which the prohibition specified in the notice takes effect, which must be not less than seven days from the date on which the notice is served¹⁴. However, where the Secretary of State considers that it is necessary in the interests of safety, he may specify in the notice that the prohibition is to take immediate effect¹⁵.

1 As to the Secretary of State see PARA 3 note 3 ante.

2 For the meanings of 'person responsible for management of a hospital blood bank' and 'hospital blood bank' see PARA 194 note 1 ante.

3 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 11(1)(a). The specified requirements are those of the Blood Safety and Quality Regulations 2005, SI 2005/50 (as amended).

4 For the meaning of 'distribution' see PARA 185 note 4 ante.

5 For the meaning of 'blood' see PARA 185 note 2 ante; and for the meaning of 'blood component' see PARA 185 note 3 ante.

6 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 11(1)(b).

7 Ie pursuant to *ibid* reg 10: see PARA 194 ante.

8 *Ibid* reg 11(1)(c).

9 *Ibid* reg 11(1). As to objections to such notices see reg 12; and PARA 196 post. It is an offence to contravene the requirements of a notice under reg 11(1): see reg 18(5); and PARA 201 post.

10 *Ibid* reg 11(4)(a).

11 Ie the notice given pursuant to *ibid* reg 11(1)(b): see the text to notes 4-6 supra.

12 *Ibid* reg 11(4)(b).

13 *Ibid* reg 11(4)(c).

14 *Ibid* reg 11(2).

15 Ibid reg 11(3).

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196. Objections to suspensions, revocations and notices.

A blood establishment¹ or a person responsible for the management of a hospital blood bank² who objects to any suspension or revocation of authorisation³ or to any notice served⁴ on it⁵, or objects to the refusal of authorisation or the imposition of any condition⁶ on an authorisation⁷, may notify the Secretary of State⁸ of its or his desire to make written representations to, or to appear before and be heard by, a person appointed by the Secretary of State for that purpose⁹. Where the Secretary of State receives such a notification, he must appoint a person to consider the matter¹⁰. The person appointed must determine the procedure to be followed with respect to the consideration of any objection¹¹, and must consider any written or oral representations made by the blood establishment or the person responsible for management of the hospital blood bank in support of the objection, and make a recommendation to the Secretary of State¹². The Secretary of State must take into account any recommendation made by the person appointed¹³ and, within 14 days of receipt thereof, must inform the blood establishment or the person responsible for the management of the hospital blood bank whether he accepts the recommendation and, if he does not accept it, of the reasons for his decision¹⁴.

Where the Secretary of State is notified of an objection¹⁵ before the date upon which the suspension or revocation or the notice is due to take effect, the suspension or revocation or notice in respect of which the objection is made does not take effect until the person appointed has considered the matter and made a recommendation¹⁶, and the Secretary of State has informed the blood establishment or the person responsible for the management of the hospital blood bank concerned of his decision with regard to the recommendation¹⁷. Where the Secretary of State is notified of an objection¹⁸, within the period specified¹⁹, to a suspension, revocation or other notice which has already taken effect on the date the notification was made, the suspension, revocation or notice in respect of which the objection is made ceases to have effect until the person appointed has considered the matter and made a recommendation²⁰, and the Secretary of State has informed the blood establishment or the person responsible for the management of the hospital blood bank concerned of his decision with regard to the recommendation²¹. However, these provisions²² do not apply in relation to a suspension or revocation, or a notice served²³ on the person responsible for management of a hospital blood bank, which takes²⁴ immediate effect²⁵, or, in any other case, where the Secretary of State determines that it is necessary in the interests of public safety for the suspension, revocation or notice to take effect on the date originally specified, and serves a notice in writing to that effect on the blood establishment or person responsible for management of the hospital blood bank concerned²⁶.

1 For the meaning of 'blood establishment' see PARA 189 note 4 ante.

2 For the meanings of 'person responsible for management of a hospital blood bank' and 'hospital blood bank' see PARA 194 note 1 ante.

3 As to the suspension or revocation of authorisation see PARA 190 ante.

4 Ie pursuant to the Blood Safety and Quality Regulations 2005, SI 2005/50, regs 4(8), 5, 11: see PARAS 189 note 12, 190, 195 ante.

5 Ibid reg 12(1)(a).

6 Ie pursuant to ibid reg 4(5): see PARA 189 note 7 ante.

7 Ibid reg 12(1)(b).

8 As to the Secretary of State see PARA 3 note 3 ante.

9 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 12(1) (amended by SI 2005/1098). Any such notification of an objection must be made within 14 days of service on the blood establishment or the person responsible for the management of the hospital blood bank of the notice to which the notification relates: Blood Safety and Quality Regulations 2005, SI 2005/50, reg 12(2).

10 Ibid reg 12(3).

11 Ibid reg 12(4).

12 Ibid reg 12(5). Such a recommendation must be made in writing to the Secretary of State, and a copy of it must be sent to the blood establishment or the person responsible for the management of the hospital blood bank concerned, or to its nominated representative: reg 12(6).

13 Ibid reg 12(7).

14 Ibid reg 12(8).

15 Ie pursuant to ibid reg 12(1)(a): see the text to notes 1-5 supra.

16 Ibid reg 12(9)(a) (amended by SI 2005/1098).

17 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 12(9)(b) (as amended: see note 16 supra).

18 Ie pursuant to ibid reg 12(1)(a): see the text to notes 1-5 supra.

19 Ie specified in ibid reg 12(2): see note 9 supra.

20 Ibid reg 12(10)(a).

21 Ibid reg 12(10)(b).

22 Ie ibid reg 12(9), (10): see the text to notes 15-21 supra.

23 Ie pursuant to ibid reg 11: see PARA 195 ante.

24 Ie in accordance with ibid regs 5(3), 11(3): see PARAS 190, 195 ante.

25 Ibid reg 12(11)(a) (amended by SI 2005/1098).

26 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 12(11)(b) (as amended: see note 25 supra).

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197. Disclosure of information.

A blood establishment¹ and the person responsible for management of a hospital blood bank² must ensure that all information which is collected³ with regard to blood⁴ safety and quality is held securely so that it is available for the purpose of tracing donations⁵, is not disclosed except in accordance with one or more of the specified requirements⁶ or where they have been rendered anonymous so that donors are no longer identifiable⁷, and is subject to safeguards against unauthorised additions, deletions or modifications⁸.

The responsible person⁹ of the blood establishment and the person responsible for management of the hospital blood bank must ensure that they put in place a procedure to ensure that any discrepancies relating to data which are brought to their attention are resolved without delay¹⁰.

1 For the meaning of 'blood establishment' see PARA 189 note 4 ante.

2 For the meanings of 'person responsible for management of a hospital blood bank' and 'hospital blood bank' see PARA 194 note 1 ante.

3 For the purposes of the Blood Safety and Quality Regulations 2005, SI 2005/50 (as amended).

4 For the meaning of 'blood' see PARA 185 note 2 ante.

5 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 14(1)(a).

6 Ibid reg 14(1)(b)(i). The specified requirements are: (1) the disclosure is made in accordance with an order of a court or is otherwise required by law (reg 14(2)(a)); (2) the disclosure is to an inspector appointed by the Secretary of State in accordance with reg 15(10) (see PARA 198 post) (reg 14(2)(b)); or (3) the disclosure is for the purpose of tracing a donation from donor to recipient or recipient to donor (reg 14(2)(c)). Where a disclosure is made to an inspector pursuant to reg 14(2)(b), the inspector must not further disclose the information received unless the disclosure is made in accordance with an order of a court or is otherwise required by law (reg 14(3)(a)), the disclosure is to another officer of the Secretary of State where this is necessary for the proper performance of the inspector or officer's duties (reg 14(3)(b)), or the information has been rendered anonymous so that that donors are no longer identifiable (reg 14(3)(c)). Where a disclosure is so made by an inspector to another officer of the Secretary of State, that person must not further disclose the information he receives other than in accordance with the requirements of reg 14(3): reg 14(4). As to the Secretary of State see PARA 3 note 3 ante.

7 Ibid reg 14(1)(b)(ii).

8 Ibid reg 14(1)(c). As to offences relating to the contravention of reg 14 see reg 18(6); and PARA 201 post.

9 For the meaning of 'responsible person' see PARA 191 note 2 ante.

10 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 14(5).

UPDATE

197 Disclosure of information

TEXT AND NOTES--A person responsible for management of a facility must ensure that the facility (1) retains data in relation to a record of data on traceability by facilities, in an appropriate and readable storage medium, for a period of at least 30 years; and (2) has in place a system to record each unit of blood or blood component received,

whether locally used, and the final destination of that received unit whether transfused, used in the manufacture of medicinal products, discarded or returned to the blood establishment or hospital blood bank: SI 2005/50 reg 12A (regs 12A, 12B added by SI 2006/2013; SI 2005/50 reg 12B amended by SI 2007/604, SI 2008/941). A person responsible for management of a reporting establishment must ensure that the reporting establishment (a) has in place procedures to retain the record of transfusions for a period of at least 30 years; (b) notifies blood establishments without delay of any serious adverse reactions observed in recipients during or after transfusion which may be attributable to the quality or safety of blood or blood components; and (c) notifies the Secretary of State as soon as is known all relevant information about suspected serious adverse reactions using the notification formats specified: SI 2005/50 reg 12B (as so added and amended). See further Schedule Pts 6-8 (added by SI 2006/2013). Contravention of SI 2005/50 reg 12A or 12B is an offence: reg 18(1)(f), (g) (added by SI 2006/2013; see PARA 201).

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198. Inspections.

The Secretary of State¹ must conduct a regular inspection² of each site³ of a blood establishment, not less than once every two years, for the purpose of ensuring that blood establishments comply with the specified requirements⁴ and problems relating to compliance with those requirements are identified⁵. The Secretary of State may conduct such additional inspections of blood establishments sites as he considers necessary for the purpose of ensuring compliance with the specified requirements⁶. The Secretary of State may also serve a notice on a blood establishment requiring that it furnish him with such information concerning its compliance with the specified requirements as are specified in the notice within such period as is so specified⁷.

The Secretary of State may inspect hospital blood banks with a view to ensuring that they and persons responsible for the management of such blood banks comply with the specified requirements⁸ and problems relating to compliance with those requirements are identified⁹. The Secretary of State may also serve a notice on the person responsible for managing a hospital blood bank requiring that he furnish him with such information concerning the compliance of the blood bank with the specified requirements as is specified in the notice within such period as is so specified¹⁰.

In the event of any serious adverse event¹¹ or any serious adverse reaction¹² or suspicion thereof, the Secretary of State must request such information or conduct such inspections in accordance with these provisions as he considers appropriate¹³.

The Secretary of State may appoint such persons to be inspectors as he thinks necessary for the proper discharge by them of his functions¹⁴; and he may appoint such persons upon such terms and conditions, including conditions as to remuneration, benefits, allowances and reimbursement for expenses, as he thinks fit¹⁵.

1 As to the Secretary of State see PARA 3 note 3 ante.

2 'Inspection' means formal and objective control to identify problems in accordance with standards adopted to assess compliance with the Blood Safety and Quality Regulations 2005, SI 2005/50 (as amended): reg 1(3).

3 Any reference to an inspection of a site which the Secretary of State is required or empowered to conduct by virtue of *ibid* reg 15 must be construed so as to include an inspection of premises within the United Kingdom at which any of the activities listed in reg 3(2) (see PARA 189 ante) are carried out by any person on behalf of, and pursuant to a contractual arrangement with, a blood establishment or, as the case may be, a person responsible for management of a hospital blood bank: reg 15(9). For the meaning of 'site' see PARA 189 note 7 ante; and for the meaning of 'blood establishment' see PARA 189 note 4 ante. For the meanings of 'person responsible for management of a hospital blood bank' and 'hospital blood bank' see PARA 194 note 1 ante.

4 *Ibid* reg 15(1)(a). The specified requirements are those of the Blood Safety and Quality Regulations 2005, SI 2005/50 (as amended).

5 *Ibid* reg 15(1)(b). Where the Secretary of State carries out an inspection at a site of a blood establishment he may charge the establishment and that establishment must, if so charged, pay to the Secretary of State a fee: reg 22(3). As to the amounts of such fees see reg 22(3)(a)-(f). Any such fee is payable within 14 days following written notice from the Secretary of State requiring payment of the fee: reg 22(7)(iii). As to fees generally see PARA 188 ante.

6 *Ibid* reg 15(2). See also note 5 supra.

7 Ibid reg 15(3). Any blood establishment which receives such a request for information must provide the information requested within the period specified in the notice: reg 15(4). It is an offence to contravene reg 15(4): see reg 18(2)(e); and PARA 201 post.

8 Ibid reg 15(5)(a).

9 Ibid reg 15(5)(b). Where the Secretary of State carries out an inspection of a hospital blood bank he may charge the person responsible for management of the hospital blood bank and that person must, if so charged, pay to the Secretary of State a fee: reg 22(4). As to the amount of such fees see reg 22(5). Any such fee is payable within 14 days following written notice from the Secretary of State requiring payment of the fee: reg 22(7)(iii).

10 Ibid reg 15(6). Any person responsible for management of a hospital blood bank who receives such a request for information must provide the information requested within the period specified in the notice: reg 15(7). It is an offence to contravene reg 15(7): see reg 18(2)(e); and PARA 201 post.

11 For the meaning of 'serious adverse event' see PARA 192 note 10 ante.

12 For the meaning of 'serious adverse reaction' see PARA 192 note 12 ante.

13 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 15(8). See also notes 5, 9 supra.

14 Ie set out in the Blood Safety and Quality Regulations 2005, SI 2005/50 (as amended).

15 Ibid reg 15(10). 'Inspector' means a person appointed by the Secretary of State to carry out inspections pursuant to reg 15(10): reg 1(3).

UPDATE

198 Inspections

NOTE 5--SI 2005/50 reg 22(3)(a), (b) (substituted for reg 22(3)(a)-(f) by SI 2008/525, and amended by SI 2009/372).

TEXT AND NOTES 8, 9--After 'blood banks' read 'and facilities': SI 2005/50 reg 15(5) (amended by SI 2006/2013).

NOTE 9--After 'hospital blood bank' read 'or facility' (in both places): SI 2005/50 reg 22(4) (amended by SI 2006/2013). SI 2005/50 reg 22(5) amended: SI 2008/525, SI 2009/372.

TEXT AND NOTE 10--After 'blood bank' read 'or a facility' (in both places): SI 2005/50 reg 15(6) (amended by SI 2006/2013).

NOTE 10--After 'hospital blood bank' read 'or a facility': SI 2005/50 reg 15(7) (amended by SI 2006/2013).

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199. Inspector's powers.

For the purposes of enforcing compliance with the specified requirements¹ or conducting inspections², and upon production of evidence that he is so authorised, an inspector³ has the right⁴:

- 162 (1) at any reasonable hour to enter any premises, other than premises used only as a private dwelling house, which he has reason to believe it is necessary for him to visit, including:
 - 19 20. (a) any premises owned or managed by a blood establishment⁵ or person responsible for management of a hospital blood bank⁶, or at which the blood establishment or person responsible for management of a hospital blood bank carries out any of the activities⁷ requiring authorisation⁸;
 21. (b) any premises of any person who carries out any such activities on behalf of, and pursuant to a contractual arrangement with, a blood establishment or a person responsible for management of a hospital blood bank⁹; and
 22. (c) where any facilities for donor evaluation and testing are in the premises of any person¹⁰ other than a blood establishment or hospital blood bank, those facilities in that person's premises¹¹;
- 20 163 (2) to carry out at those premises during that visit inspections, examinations, tests and analyses as he considers necessary¹²;
- 164 (3) to require the production of, and inspect, any article or substance at the premises¹³;
- 165 (4) to require the production of, inspect and take copies of, or extracts from, any book, document, data or record, in whatever form it is held, at, or in the case of computer data or records accessible at, the premises¹⁴;
- 166 (5) to take possession of any samples for examination and analysis and any other article, substance, book, document, data or record, in whatever form they are held, at, or in the case of computer data or records accessible at, the premises¹⁵;
- 167 (6) to question any person whom he finds at the premises and whom he has reasonable cause to believe is able to give him relevant information¹⁶;
- 168 (7) to require any person to afford him such assistance as he considers necessary with respect to any matter within that person's control, or in relation to which that person has responsibilities¹⁷;
- 169 (8) to require, as he considers necessary, any person to afford him such facilities as he may reasonably require that person to afford him¹⁸.

If a justice of the peace¹⁹ is satisfied by any written information on oath²⁰ that there are reasonable grounds for entry into any premises, other than premises used only as a private dwelling house, for any purpose mentioned in heads (1) to (8) above, and certain conditions are met²¹, the justice may by warrant signed by him authorise an inspector to enter the premises, if need be by force²².

An inspector entering premises by virtue of his powers of entry under heads (1) to (8) above or of a warrant may take with him when he enters those premises such equipment as may appear

to him necessary and any person who is authorised by the Secretary of State²³ to accompany him on that visit²⁴.

On leaving any premises which an inspector is authorised to enter by a warrant, he must, if the premises are unoccupied or the occupier is temporarily absent, leave the premises as effectively secured against trespassers as he found them²⁵. Where, pursuant to head (5) above, an inspector takes possession of any article, substance, book, document, data or record, he must leave at the premises with a responsible person, or if there is no such person present on the premises, leave in the premises in a prominent position, a statement giving particulars of the article, substance, book, document, data or record sufficient to identify it and stating that he has taken possession of it²⁶; and where, pursuant to head (5) above, an inspector takes a sample for analysis, the Secretary of State may make such arrangements for analysis of that sample as he considers appropriate²⁷.

1 Ie the Blood Safety and Quality Regulations 2005, SI 2005/50 (as amended).

2 Ie pursuant to *ibid* reg 15: see PARA 198 ante. For the meaning of 'inspection' see PARA 198 note 2 ante.

3 For the meaning of 'inspector' see PARA 198 note 15 ante.

4 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 17(1). Nothing in reg 17(1) may be taken to compel the production by any person of a document of which he would on grounds of legal professional privilege be entitled to withhold production on an order for disclosure in an action in the High Court: reg 17(1). As to legal professional privilege see CIVIL PROCEDURE vol 11 (2009) PARAS 558 et seq, 972. It is an offence to obstruct an inspector, to fail to comply with any requirements made by an inspector or to give false or misleading information in purported compliance with such a requirement: see reg 18(7), (8); and PARA 201 post.

5 For the meaning of 'blood establishment' see PARA 189 note 4 ante.

6 For the meanings of 'person responsible for management of a hospital blood bank' and 'hospital blood bank' see PARA 194 note 1 ante.

7 Ie referred to in the Blood Safety and Quality Regulations 2005, SI 2005/50, reg 3: see PARA 189 ante.

8 *Ibid* reg 17(1)(a)(i).

9 *Ibid* reg 17(1)(a)(ii).

10 For the meaning of 'person' see PARA 21 note 7 ante.

11 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 17(1)(a)(iii).

12 *Ibid* reg 17(1)(b).

13 *Ibid* reg 17(1)(c).

14 *Ibid* reg 17(1)(d). See also note 4 *supra*.

15 *Ibid* reg 17(1)(e) (amended by SI 2005/1098). See also note 4, and the text to notes 26-27 *infra*.

16 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 17(1)(f).

17 *Ibid* reg 17(1)(g). See also note 4 *supra*.

18 *Ibid* reg 17(1)(h).

19 As to justices of the peace see MAGISTRATES vol 29(2) (Reissue) PARA 501 et seq.

20 As to oaths, affirmations and declarations see CIVIL PROCEDURE vol 11 (2009) PARA 1021 et seq.

21 The conditions are that: (1) admission to the premises has been refused or is likely to be refused and notice of intention to apply for a warrant has been given to the occupier (Blood Safety and Quality Regulations 2005, SI 2005/50, reg 17(2)(a)); (2) an application for admission, or the giving of such notice, would defeat the

object of the entry (reg 17(2)(b)); or (3) the premises are unoccupied or the occupier is temporarily absent and it might defeat the object of the entry to await his return (reg 17(2)(c)).

22 Ibid reg 17(2). Such a warrant continues in force for a period of one month: reg 17(2). For the meaning of 'month' see PARA 22 note 15 ante.

23 As to the Secretary of State see PARA 3 note 3 ante.

24 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 17(3).

25 Ibid reg 17(4).

26 Ibid reg 17(5).

27 Ibid reg 17(6). In such a case, the Secretary of State must inform the responsible person of the blood establishment or person responsible for the management of the hospital blood bank from which the sample was taken that he intends to make arrangements for analysis of the sample, and of the tests which he intends should be made (reg 17(7)(a)); and if the responsible person or person responsible for the management of the hospital blood bank so requests, the Secretary of State must divide the sample of which an analysis is to be made into three equal parts (reg 17(7)(b)). If the sample is so divided, the parts must be dealt with as follows: (1) the Secretary of State must make arrangements for the testing of one part of the sample (reg 17(8)(a)); (2) one part of the sample must be sent to the responsible person of the blood establishment or person responsible for the management of the hospital blood bank (reg 17(8)(b)); and (3) one part of the sample must be retained by the Secretary of State for a reasonable period in case of dispute (reg 17(8)(c)). For the meaning of 'responsible person' see PARA 191 note 2 ante.

UPDATE

199 Inspector's powers

TEXT AND NOTE 9--Head (b), for 'and' in the first place where that term appears, substitute 'or': SI 2005/50 reg 17(1)(a)(ii) (amended by SI 2006/2013).

TEXT AND NOTE 11--Also head (d) any premises where transfusion of blood or blood components takes place, or which are owned or managed by a person responsible for management of a facility to which blood or blood components have been delivered: SI 2005/50 reg 17(1)(a)(iv) (added by SI 2006/2013).

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200. Records to be kept by the Secretary of State.

The Secretary of State¹ must keep such records of information which he receives from, or relating to, blood establishments² as he considers appropriate and must, in particular, keep records relating to authorisations³, the designation⁴ of responsible persons⁵, notification⁶ of serious adverse events⁷ and serious adverse reactions⁸ by such establishments⁹, and inspections or requests for information¹⁰.

The Secretary of State must also keep such records of information which he receives from persons responsible for management of hospital blood banks¹¹, or otherwise or relating to hospital blood banks, as he considers appropriate and must, in particular, keep records relating to notification¹² of serious adverse events and serious adverse reactions¹³, the information supplied¹⁴ by hospital blood banks in annual reports¹⁵, and inspections or requests for information¹⁶.

1 As to the Secretary of State see PARA 3 note 3 ante.

2 For the meaning of 'blood establishment' see PARA 189 note 4 ante.

3 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 16(1)(a). As to authorisations see reg 4; and PARA 189 ante.

4 *Ie* under *ibid* reg 6: see PARA 191 ante.

5 *Ibid* reg 16(1)(b).

6 *Ie* pursuant to *ibid* reg 7(1)(e): see PARA 192 ante.

7 For the meaning of 'serious adverse event' see PARA 192 note 10 ante.

8 For the meaning of 'serious adverse reaction' see PARA 192 note 12 ante.

9 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 16(1)(c).

10 *Ibid* reg 16(1)(d). As to inspections and requests for information see reg 15; and PARA 198 ante. Records must also be kept of the operation, during the period from 8 February 2005 to 7 November 2005, of blood establishments licensed under the Medicines Act 1968 s 8 (as amended) (see PARAS 46-47 ante): Blood Safety and Quality Regulations 2005, SI 2005/50, reg 16(1)(e) (amended by SI 2005/1098).

11 For the meanings of 'person responsible for management of a hospital blood bank' and 'hospital blood bank' see PARA 194 note 1 ante.

12 *Ie* pursuant to the Blood Safety and Quality Regulations 2005, SI 2005/50, reg 9(1)(f): see PARA 194 ante.

13 *Ibid* reg 16(2)(a).

14 *Ie* pursuant to *ibid* reg 10: see PARA 194 ante.

15 *Ibid* reg 16(2)(b).

16 *Ibid* reg 16(2)(c). As to inspections and requests for information see reg 15; and PARA 198 ante.

UPDATE

200 Records to be kept by the Secretary of State

TEXT AND NOTES--The Secretary of State must communicate to the competent authorities of other member states such information as is appropriate with regard to serious adverse reactions and events in order to guarantee that blood or blood components known or suspected to be defective are withdrawn from use and discarded: SI 2005/50 reg 16A (added by SI 2006/2013).

NOTES 6, 9--For 'reg 7(1)(e)' read 'reg 12B': SI 2005/50 reg 16(1)(c) (amended by SI 2007/604).

TEXT AND NOTE 11--After 'hospital blood banks' read 'and facilities': SI 2005/50 reg 16(2) (amended by SI 2006/2013).

NOTES 12, 13--For 'reg 9(1)(f)' read 'reg 12B': SI 2005/50 reg 16(2)(a) (amended by SI 2007/604).

TEXT AND NOTE 12--After 'otherwise' omit 'or' and after 'hospital blood banks' read 'of facilities': SI 2005/50 reg 16(2) (amended by SI 2006/2013).

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(iii) Offences

201. Offences.

A person¹ is guilty of an offence if he contravenes any of the provisions relating to²:

- 170 (1) the requirement³ for authorisation⁴;
- 171 (2) the blood establishment⁵ requirements⁶;
- 172 (3) the hospital blood bank⁷ requirements⁸;
- 173 (4) the importation of blood and blood components⁹;
- 174 (5) specific epidemiological situations¹⁰;
- 175 (6) making any substantial change in the activities of a blood establishment¹¹;
- 176 (7) the responsible person for a blood establishment¹²;
- 177 (8) the labelling of blood and blood components and traceability¹³;
- 178 (9) the provision of information by hospital blood banks to the Secretary of State¹⁴;
- 179 (10) the provision of other information to the Secretary of State¹⁵.

A person is guilty of an offence¹⁶ if he is a person who:

- 180 (a) fails to comply with a notice¹⁷ of suspension or revocation of his authorisation, save where the operation of that notice has been suspended¹⁸, or has been withdrawn or revoked by the Secretary of State¹⁹;
- 181 (b) knowingly sells or supplies blood or any blood component which is not labelled²⁰ in accordance with the appropriate requirements²¹;
- 182 (c) contravenes the requirements of any notice served²² by the Secretary of State in relation to hospital blood banks²³;
- 183 (d) contravenes the provisions²⁴ relating to the disclosure of information by blood establishments and hospital blood banks²⁵, or discloses any information²⁶ to which he has access²⁷ otherwise than in accordance with one or more of the permitted requirements²⁸;
- 184 (e) intentionally obstructs an inspector²⁹; or without reasonable cause fails to comply with any requirements made of him by an inspector, in circumstances where that inspector is acting in pursuance of any of his permitted functions³⁰; or, in purported compliance with any such requirement, intentionally or recklessly furnishes information which is false or misleading in a material respect³¹.

A person guilty of any such offence is liable to a penalty³².

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 18(1), (2). As to defences to these offences see PARA 203 post; and as to offences by bodies corporate see PARA 202 post.

3 *Ie* under *ibid* reg 3(1): see PARA 189 ante.

4 *Ibid* reg 18(1)(a).

5 For the meaning of 'blood establishment' see PARA 189 note 4 ante.

6 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 18(1)(b). The blood establishment requirements are those of reg 7: see PARA 192 ante.

7 For the meaning of 'hospital blood bank' see PARA 194 note 1 ante.

8 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 18(1)(c). The hospital blood bank requirements are those of reg 9: see PARA 194 ante.

9 Ibid reg 18(1)(d). The provisions referred to in the text are those of reg 13: see PARA 186 ante. For the meaning of 'blood' see PARA 185 note 2 ante; and for the meaning of 'blood component' see PARA 185 note 3 ante.

10 Ibid reg 18(1)(e). The provisions referred to in the text are those of reg 23(2): see PARA 187 ante.

11 Ibid reg 18(2)(a). The provisions referred to in the text are those of reg 4(9): see PARA 189 ante.

12 Ibid reg 18(2)(b). The provisions referred to in the text are those of reg 6 (other than reg 6(3)): see PARA 191 ante.

13 Ibid reg 18(2)(c). The provisions referred to in the text are those of reg 8: see PARA 193 ante.

14 Ibid reg 18(2)(d). The provisions referred to in the text are those of reg 10: see PARA 194 ante. As to the Secretary of State see PARA 3 note 3 ante.

15 Ibid reg 18(2)(e). The provisions referred to in the text are those of reg 15(4), (7): see PARA 198 ante.

16 As to defences to these offences see PARA 203 post; and as to offences by bodies corporate see PARA 202 post.

17 Is served pursuant to the Blood Safety and Quality Regulations 2005, SI 2005/50, reg 5: see PARA 190 ante.

18 Is pursuant to ibid reg 12: see PARA 196 ante.

19 Ibid reg 18(3).

20 Is in accordance with the requirements of ibid reg 8: see PARA 193 ante.

21 Ibid reg 18(4).

22 Is under ibid reg 11(1): see PARA 195 ante.

23 Ibid reg 18(5).

24 Is ibid reg 14: see PARA 197 ante.

25 Ibid reg 18(6)(a).

26 Is referred to in ibid reg 14(1): see PARA 197 ante.

27 Is by virtue of the Blood Safety and Quality Regulations 2005, SI 2005/50 (as amended).

28 Ibid reg 18(6)(b). The permitted requirements are those specified in reg 14(2), (3): see PARA 197 ante.

29 Ibid reg 18(7)(a)(i). For the meaning of 'inspector' see PARA 198 note 15 ante.

30 Ibid reg 18(7)(a)(ii) (amended by SI 2005/2898). An inspector's permitted functions are those under the Blood Safety and Quality Regulations 2005, SI 2005/50 (as amended). Nothing in reg 18(7)(a)(ii) may be construed as requiring any person to answer any question or give any information if to do so might incriminate him or, in the case of a person who is married or a civil partner, his spouse or civil partner: reg 18(8).

31 Ibid reg 18(7)(a)(iii).

32 A person guilty of an offence under heads (1)-(5), (a), (c) or (e) in the text is liable on summary conviction to a fine not exceeding the statutory maximum or to imprisonment for a term not exceeding three months or to both (ibid reg 19(1)(a) (amended by SI 2005/1098)), or on conviction on indictment to a fine or to imprisonment

for a term not exceeding two years or to both (Blood Safety and Quality Regulations 2005, SI 2005/50, reg 19(1) (b)). As to the statutory maximum see PARA 32 note 3 ante. A person guilty of an offence under heads (6)-(10), (b) or (d) in the text is liable on summary conviction to a fine not exceeding level 5 on the standard scale, or to imprisonment for a term not exceeding three months or to both: reg 19(2) (amended by SI 2005/1098). As to the standard scale see PARA 6 note 22 ante.

UPDATE

201 Offences

TEXT AND NOTE 15--Also heads (11) the requirement that facilities retain certain data; (12) the requirement to report serious adverse reactions and events: SI 2005/50 reg 18(1)(f), (g) (added by SI 2006/2013). The provisions referred to are those of SI 2005/50 regs 12A and 12B: see PARA 196.

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202. Offences by bodies corporate.

Where an offence under the regulations relating to blood safety and quality¹ is committed by a body corporate² and is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, any director, manager, secretary³, or any person who was purporting to act in any such capacity⁴, he, as well as the body corporate, is deemed to be guilty of that offence and is liable to be proceeded against and punished accordingly⁵.

1 As to offences under the Blood Safety and Quality Regulations 2005, SI 2005/50 (as amended) see PARA 201 ante.

2 As to bodies corporate see COMPANIES; CORPORATIONS.

3 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 21(a).

4 Ibid reg 21(b).

5 Ibid reg 21.

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203. Defence of due diligence.

In any proceedings for an offence under the regulations relating to blood safety and quality¹, it is a defence for the person² charged to prove that he took all reasonable precautions and exercised all due diligence to avoid commission of the offence³. Where evidence is adduced which is sufficient to raise an issue with respect to that defence, the court or jury must assume that the defence is satisfied unless the prosecution proves beyond all reasonable doubt that it is not⁴.

1 As to offences under the Blood Safety and Quality Regulations 2005, SI 2005/50 (as amended) see PARA 201 ante.

2 For the meaning of 'person' see PARA 21 note 7 ante.

3 Blood Safety and Quality Regulations 2005, SI 2005/50, reg 20(1). As to the standard of proof on the accused see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(3) (2006 Reissue) PARA 1372.

4 Ibid reg 20(2).

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(13) HOMOEOPATHIC MEDICINAL PRODUCTS

(i) Products for Human Use

204. Advisory Board on the Registration of Homoeopathic Products.

The Advisory Board on the Registration of Homoeopathic Products is a committee¹ established for the purpose of giving advice with respect to the safety² and quality of any homoeopathic medicinal product³ in respect of which the specified conditions⁴ are met and to which any provision of the Medicines Act 1968 is applicable⁵. The specified conditions are: (1) the product is one to which the European Community code⁶ relating to medicinal products for human use applies⁷; (2) the product is for oral or external administration⁸; (3) no specific therapeutic indication appears on the labelling⁹ of the product or in any information relating thereto¹⁰; (4) the product is one in respect of which an application for a certificate of registration¹¹ has been made¹², or an application¹³ for the renewal of such a certificate has been made¹⁴, or the licensing authority¹⁵ proposes to suspend vary or revoke the certificate of registration¹⁶.

1 The Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1995, SI 1995/309 (as amended) is made under the Medicines Act 1968 s 4 (as amended) which relates to the establishment of committees: see PARA 15 ante.

2 As to considerations of safety see PARA 15 note 10 ante.

3 'Homoeopathic medicinal product' means a medicinal product (which may contain a number of principles) prepared from substances called homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by any pharmacopoeia used officially in a member State: Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1995, SI 1995/309, art 1(2) (definition amended by SI 2005/2753).

4 Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1995, SI 1995/309, art 2(1)(a). As to the conditions see heads (1)-(4) in the text.

5 Ibid art 2(1).

6 Ie EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) on the Community code relating to medicinal products for human use, as amended by EC Parliament and Council Directive 2002/98 (OJ L33, 8. 2. 2003, p 30), EC Commission Directive 2003/63 (OJ L159, 27.6.2003, p 46), EC Parliament and Council Directive 2004/24 (OJ L136, 30.4.2004, p 85) and EC Parliament and Council Directive 2004/27 (OJ L136, 30.4.2004, p 34).

7 Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1995, SI 1995/309, art 2(2)(a) (amended by SI 2002/236, SI 2005/2753).

8 Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1995, SI 1995/309, art 2(2)(b). As to the meaning of 'administer' see PARA 7 note 2 ante.

9 For the meaning of 'labelling' see PARA 152 note 4 ante.

10 Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1995, SI 1995/309, art 2(2)(c).

11 Ie in accordance with the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 4(1): see PARA 205 post. 'Certificate of registration' means a certificate for the purposes of the

Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105 (as amended):
Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1995, SI 1995/309, art 1(2).

12 Ibid art 2(2)(d)(i).

13 le in accordance with the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 8(2): see PARA 206 post.

14 Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1995, SI 1995/309, art 2(2)(d)(ii) (amended by SI 2005/2753).

15 For the meaning of 'the licensing authority' see PARA 43 note 8 ante.

16 Medicines (Advisory Board on the Registration of Homoeopathic Products) Order 1995, SI 1995/309, art 2(2)(d)(iii) (amended by SI 2005/2753).

UPDATE

204 Advisory Board on the Registration of Homoeopathic Products

TEXT AND NOTES--Replaced. The Board's purpose is to give advice with respect to (1) the safety and quality of any homoeopathic medicinal product (a) in respect of which a certificate of registration has been granted, or (b) which is the subject of an application for such a certificate; and (2) the safety, quality and efficacy of any homoeopathic medicinal product (a) in respect of which a marketing authorisation has been granted, (b) which is the subject of an application for such an authorisation, or (c) in respect of which a licence of right has been granted: SI 1995/309 art 2(1)(a), (b) (art 2(1) amended, art 2(2) revoked by the Medicines (Advisory Board on the Registration of Homoeopathic Products) Amendment Order 2006, SI 2006/2386). 'Marketing authorisation' means a marketing authorisation for a national homoeopathic product granted by the licensing authority under the Medicines for Human Use (Marketing Authorisation Etc) Regulations 1994, SI 1994/3144: SI 1995/309 art 1(2) (added by SI 2006/2386).

NOTE 6--Directive 2001/83 further amended: European Parliament and EC Council Regulations 1901/2006 (OJ L378, 27.12.2006, p 1), 1394/2007 (OJ L324, 10.12.2007, p 121) and European Parliament and EC Council Directive 2008/29 (OJ L81, 20.3.2008, p 51).

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205. Certificates of registration.

A certificate of registration¹ authorises the placing on the market² of a homoeopathic medicinal product³. Every application for the grant or renewal of a certificate of registration must be made in writing⁴ in accordance with the provisions of the Directive on the Community code relating to medicinal products for human use⁵ and the applicant must comply with so much of the provisions of the Directive as contain requirements for applications, and as are applicable to the application or the consideration of it⁶. An application for such a certificate may relate to a series of homoeopathic medicinal products derived from the same homoeopathic stock or stocks⁷.

Every holder⁸ of a certificate of registration must comply with all obligations which relate to him by virtue of the Directive⁹, and must keep such documents as will facilitate the withdrawal or recall from sale or supply of any homoeopathic medicinal product to which the certificate relates¹⁰. Where, by or under any provision of the Directive or the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, a person¹¹ is required to provide any information or furnish any document to the licensing authority¹² and no time is specified in that provision within which that obligation is to be performed, it must be performed within such time as may be specified in a written notice served on that person by the licensing authority¹³.

1 'Certificate of registration' means a certificate for the purposes of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105 (as amended): reg 1(2). The requirement in EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 56a for the name of the homoeopathic medicinal product to be expressed in Braille format on the packaging does not apply until 30 October 2010 for products in relation to which the certificate of registration was granted before 30 October 2005: Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 20, Sch 7 para 1 (reg 20, Sch 7 added by SI 2005/2753). Until 30 October 2010, the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105 (as amended) apply, in so far as they relate to the labelling of medicinal products in respect of which a certificate of registration was granted before 30 October 2005, as if EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) had not been amended by EC Parliament and Council Directive 2004/27 (OJ L36, 30.4.2004, p 34) art 1(51): Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, Sch 7 para 2 (as so added).

2 Any expressions which are also used in EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) (as amended) have the same meanings as they have that Directive; and related expressions must be construed accordingly: Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 1(2) (definition added by SI 2002/236; and amended by SI 2003/2321; SI 2005/2753); Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 1(3)(c) (substituted by SI 2005/2753).

3 Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 3. The Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105 (as amended) apply to homoeopathic medicinal products for human use to which EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) (as amended) applies and that fulfil the conditions laid down in art 14(1) other than those prepared in accordance with a magistral or official formula as defined in art 3 or which satisfy the criteria laid down in art 5: Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 2 (amended by SI 2002/236; SI 2005/2753). 'Homoeopathic medicinal product' means a medicinal product (which may contain a number of principles) prepared from substances called homoeopathic stocks in accordance with a homoeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by any pharmacopoeia used officially in a member state: Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 1(2) (definition amended by SI 2005/2753). As to the European Pharmacopoeia see PARA 148 note 24 ante. For the meaning of 'member state' see the European Communities Act 1972 s 1(2), Sch 1 Pt II; and the Interpretation Act 1978 s 5, Sch 1.

Various provisions of the Medicines Act 1968 have effect in relation to certificates of registration as they have effect in relation to product licences, subject to specified modifications: see the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 19(1), (2), Sch 4 (amended by SI 2005/2753). Those provisions are the Medicines Act 1968 s 23 (see PARA 66 ante), s 44 (see PARAS 57, 70, 80 ante), s 46 (see PARA 177 ante), ss 58A-59 (s 58A as added and amended; s 58B as added) (see PARAS 141-142 ante), ss 92-94 (see PARAS 157-161 ante), ss 96-97 (see PARAS 164-166 ante), s 107 (see PARA 79 ante), ss 108-112 (see PARAS 168-170 ante), ss 118-119 (see PARAS 174-175 ante), ss 121-122, 124 (see PARAS 179-181 ante), s 126 (see PARA 184 ante) and s 127 (see PARA 37 note 8 ante).

4 For the meaning of 'writing' see PARA 21 note 6 ante; definition applied by the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 1(2).

5 The EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) on the Community code relating to medicinal products for human use (amended by EC Parliament and Council Directive 2002/98 (OJ L33, 8. 2. 2003, p 30), EC Commission Directive 2003/63 (OJ L159, 27.6.2003, p 46), EC Parliament and Council Directive 2004/24 (OJ L136, 30.4.2004, p 85), and EC Parliament and Council Directive 2004/27 (OJ L136, 30.4.2004, p 34)).

6 Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 4(1) (substituted by SI 2005/2753). As to provisions relating to fees see PARA 211 post.

7 Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 4(2). General awareness of the homoeopathic medicinal product is not among the conditions which a medicinal product must satisfy in order to satisfy the registration procedure. It is not necessary that the homoeopathic character of the medicinal product prepared from one or more stocks must be proved, and its safety in homoeopathic use demonstrated. It is necessary only that the homoeopathic stock or stocks from which that product is derived must be well-known. Thus a national provision which does not permit the registration of a medicinal product composed of several known homoeopathic substances where its use as a homoeopathic medicinal product is not generally known is unlawful: Case C-444/03 *Meta Fackler KG v Germany* [2005] All ER (D) 162 (May), ECJ.

8 Any reference to the holder of a certificate of registration must be construed as a reference to the holder of such a certificate which is for the time being in force: Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 1(3)(b).

9 Ibid reg 7A(1) (reg 7A added by SI 2005/2753). As to offences by the holder of a certificate see PARA 209 post.

10 Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 7A(2) (as added: see note 9 supra). As to withdrawal of products from the market see PARA 210 post.

11 For the meaning of 'person' see PARA 21 note 7 ante.

12 For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 1(2). See also PARA 206 note 1 post.

13 Ibid reg 7A(4) (as added: see note 9 supra).

UPDATE

205 Certificates of registration

NOTE 5--Directive 2001/83: further amended: European Parliament and EC Council Regulations 1901/2006 (OJ L378, 27.12.2006, p 1), 1394/2007 (OJ L324, 10.12.2007, p 121) and European Parliament and EC Council Directive 2008/29 (OJ L81, 20.3.2008, p 51).

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206. Grant, renewal, revocation, suspension or variation of certificates of registration.

The licensing authority¹ must consider every application for the grant of a certificate of registration² in accordance with the provisions of the Directive on the Community code relating to medicinal products for human use³ and must grant or refuse to grant the certificate in accordance with those provisions⁴. Before granting or refusing to grant a certificate of registration the licensing authority must follow the appropriate procedure⁵. Where a certificate of registration is granted, the appropriate ministers⁶ must determine which, if any, of their powers relating to general sale lists⁷ and medicinal products on prescription only⁸ they propose to exercise in respect of that product⁹.

A certificate of registration expires, unless previously revoked, at the end of the period of five years beginning with the date on which it was granted¹⁰. A certificate which has not been revoked may, on the application of the holder of the certificate¹¹, be renewed¹² by the licensing authority¹³. Before renewing or refusing to renew a certificate of registration the licensing authority must follow the appropriate procedure¹⁴.

The licensing authority may and, where appropriate must, revoke, suspend or vary a certificate of registration¹⁵. Before making any revocation, variation or suspension of a certificate of registration the licensing authority must follow the appropriate procedure¹⁶.

1 For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 1(2). In so far as they relate to homoeopathic medicinal products to which the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105 (as amended) apply and fall to be performed by, or by any authority of, the United Kingdom, the functions of a member state, or of the competent authority of a member state, under any of the provisions of EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) (as amended) are to be performed by the licensing authority, except in so far as any such functions fall to be performed by the exercise of any powers or duties which are conferred by any provision of the regulations, or by any provision of the Medicines Act 1968 as applied by the regulations, on a person or body other than the licensing authority: Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 2A(1), (2) (reg 2A added by SI 2005/2753). For the meaning of 'United Kingdom' see PARA 7 note 3 ante. For the meaning of 'member state' see the European Communities Act 1972 s 1(2), Sch 1 Pt II; and the Interpretation Act 1978 s 5, Sch 1.

2 For the meaning of 'certificate of registration' see PARA 205 note 1 ante.

3 Ie EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) (as amended).

4 Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 5(1) (reg 5(1), (4) substituted by SI 2005/2753).

5 See the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 5(4) (as substituted: see note 4 supra). As to the procedure see PARAS 207-208 post.

6 For the meaning of 'the appropriate ministers' see PARA 4 ante; definition applied by ibid reg 1(2).

7 Ie under the Medicines Act 1968 s 51(1): see PARA 133 ante.

8 Ie under ibid s 58(1): see PARA 140 ante. The provisions of s 58A (as added) and s 59 relating to prescription only medicines (see PARAS 141-142 ante) apply with modifications for the purposes of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105 (as amended): see Sch 4.

9 Ibid reg 6(a).

10 Ibid reg 8(1) (reg 8(1) amended, and reg 8(2A) added, by SI 2005/2753). However, a certificate of registration ceases to be valid if the homoeopathic medicinal product in respect of which it was granted is not placed on the market in the United Kingdom for a period of three consecutive years: Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 8(2A) (as so added). For the meaning of 'homoeopathic medicinal product' see PARA 205 note 3 ante.

11 As to references to the holder of a certificate of registration see PARA 205 note 8 ante.

12 Ie in accordance with the provisions of EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) (as amended).

13 Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 8(2) (amended by SI 2005/2753).

14 See the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 8(5) (added by SI 2005/2753). As to the procedure see PARAS 207-208 post.

15 Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 9(1) (reg 9 substituted by SI 2005/2753). Any such revocation, suspension or variation is subject to and in accordance with the provisions of EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) (as amended): Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 9(1) (as so substituted).

16 See ibid reg 9(2) (as substituted: see note 15 supra). As to the procedure see PARAS 207-208 post.

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207. Procedures relating to certificates of registration.

In respect of any application¹ for the grant of a certificate of registration² for a homoeopathic medicinal product³, or any application to renew a certificate of registration for a homoeopathic medicinal product⁴, or any proposal to revoke, vary or suspend a certificate of registration for a homoeopathic medicinal product other than a variation on the application of the holder of that certificate of registration⁵, the licensing authority must not refuse to grant or renew the certificate of registration applied for⁶, or revoke, vary or suspend⁷ a certificate of registration⁸, on grounds relating to safety or quality, except after consultation with the appropriate committee⁹.

Where the appropriate committee is consulted and is of the provisional opinion that, on grounds relating to safety or quality, it may be unable to advise the licensing authority to grant or renew the certificate of registration¹⁰, or may be unable to advise the licensing authority to grant it unless it contains provisions otherwise than in accordance with the application¹¹, or may have to advise the licensing authority that the certificate of registration ought to be revoked, varied or suspended¹², the appropriate committee must notify the applicant or holder accordingly¹³. A person¹⁴ who has been so notified may, within the time allowed¹⁵, give notice of his wish to make written or oral representations to the appropriate committee¹⁶, and the appropriate committee must give the applicant or holder an opportunity to make such representations¹⁷. The appropriate committee must take into account such representations as are made¹⁸ and report its findings and advice to the licensing authority, together with the reasons for its advice¹⁹.

After receiving the report of the appropriate committee the licensing authority must decide whether to refuse to grant or renew the certificate of registration, or to grant or renew it otherwise than in accordance with the application, or to proceed further with the proposal to revoke, vary or suspend the certificate of registration²⁰, and take the report into account when making its decision²¹. The licensing authority must then notify the applicant or holder of its decision²² and the advice given to it by the appropriate committee and the reasons for that advice²³. A person to whom such a notification has been given may, within the time allowed, notify the licensing authority that he wishes to appear before and be heard by a person appointed by the licensing authority with respect to the decision²⁴.

If the appropriate committee was consulted²⁵ but did not give a provisional opinion²⁶ and the licensing authority proposes: (1) to determine an application in a way which differs from the advice of the committee²⁷; (2) to revoke, vary or suspend a certificate of registration against such advice²⁸; or (3) on grounds not relating to safety or quality, not to grant or renew a certificate of registration²⁹, to grant or renew a certificate of registration otherwise than in accordance with an application³⁰, or to revoke, vary or suspend a certificate of registration³¹, the licensing authority must notify the applicant or holder accordingly³². If the appropriate committee has not been consulted³³ and the licensing authority proposes, on grounds not relating to safety or quality, not to grant or renew a certificate of registration³⁴, to grant or renew a certificate of registration otherwise than in accordance with an application³⁵, or to revoke, vary or suspend a certificate of registration³⁶, the licensing authority must notify the applicant or holder accordingly³⁷. A person to whom such a notification³⁸ has been given may, within the time allowed, notify the licensing authority that he wishes to appear before and be heard by a person appointed for the purpose by the licensing authority³⁹, or make representations in writing to the licensing authority with respect to the proposal referred to in

the notification⁴⁰. If the applicant makes written representations, the licensing authority must take those representations into account before determining the matter⁴¹.

1 Ile except one made pursuant to the procedure in EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 28.

2 For the meaning of 'certificate of registration' see PARA 205 note 1 ante.

3 Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, regs 5(4), 8(5), 9(2), Sch 5 para 2(a) (regs 5(4), 9(2) substituted, and reg 8(5), Sch 5 added, by SI 2005/2753). For the meaning of 'homoeopathic medicinal product' see PARA 205 note 3 ante. As to applications for certificates of registration see PARAS 205-206 ante. The Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, Sch 5 (as added) does not apply if the licensing authority: (1) declines to assess an application because an application for an EC registration in another EEA state is being examined in that state and the application to the licensing authority has not been submitted in accordance with EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 28(1), (3) (Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, Sch 5 para 4(a) (as so added)); or (2) rejects an application where the homoeopathic medicinal product in question has an EC registration in another EEA state and the application has not been submitted in accordance with EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 28(1), (2) (Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, Sch 5 para 4(b) (as so added)). 'EC registration' means a registration granted by a competent authority of an EEA state in accordance with the procedure set out in EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 14; and 'EEA state' means a member state, Norway, Iceland or Liechtenstein: Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 1(2) (definitions added by SI 2005/2753). For the meaning of 'member state' see the European Communities Act 1972 s 1(2), Sch 1 Pt II; and the Interpretation Act 1978 s 5, Sch 1. For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 1(2). See also PARA 206 note 1 ante.

4 Ibid Sch 5 para 2(b) (as added: see note 3 supra). As to the renewal of certificates of registration see PARA 206 ante.

5 Ibid Sch 5 para 2(c) (as added: see note 3 supra). As to the revocation, variation or suspension of a certificate of registration see PARA 206 ante. As to references to the holder of a certificate of registration see PARA 205 note 8 ante.

6 Ibid Sch 5 para 5(a) (as added: see note 3 supra).

7 Ibid Sch 5 para 5 (as added) does not apply to the suspension of a certificate of registration (whether or not it applies to any existing proposal to suspend or revoke the certificate) where it appears to the licensing authority that, in the interests of safety, it is necessary to suspend the certificate with immediate effect for a period not exceeding three months: Sch 5 para 10(1) (as added: see note 3 supra). Where the licensing authority so suspends a certificate of registration it must report the suspension forthwith to the appropriate committee: Sch 5 para 10(2) (as so added). If, after suspending a certificate of registration with immediate effect, it appears to the licensing authority or the appropriate committee advises, that the certificate of registration ought to be further suspended, or ought to be varied or revoked, the licensing authority must proceed in accordance with the applicable provisions of Sch 5 (as added), including Sch 5 para 10 (as added): Sch 5 para 11 (as so added). For the meaning of 'the appropriate committee' see PARA 15 note 5 ante; definition applied by reg 1(2).

8 Ibid Sch 5 para 5(b) (as added: see note 3 supra).

9 Ibid Sch 5 para 5 (as added: see note 3 supra).

10 Ibid Sch 5 para 6(1)(a) (as added: see note 3 supra).

11 Ibid Sch 5 para 6(1)(b) (as added: see note 3 supra).

12 Ibid Sch 5 para 6(1)(c) (as added: see note 3 supra).

13 Ibid Sch 5 para 6(1) (as added: see note 3 supra).

14 For the meaning of 'person' see PARA 21 note 7 ante.

15 'The time allowed' means the period of 28 days beginning with the date of the relevant notification, or such longer period as the licensing authority may allow in any particular case: Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, Sch 5 para 1 (as added: see note 3 supra).

16 Ibid Sch 5 para 6(2) (as added: see note 3 supra).

17 Ibid Sch 5 para 6(3) (as added: see note 3 supra). The applicant or holder must provide the appropriate committee with his written representations or a written summary of the oral representations he intends to make and any documents on which he wishes to rely in support of those representations, before the end of the period of six months beginning with the date of his notice or within such shorter period as the appropriate committee may specify in its notification: Sch 5 para 6(4) (as so added). If the applicant or holder so requests, the appropriate committee may extend the time limit up to a maximum period of 12 months beginning with the date of that persons notice: Sch 5 para 6(5) (as so added). The applicant or holder may not submit any additional written representations or documents once the time limit has expired, except with the permission of the appropriate committee: Sch 5 para 6(6) (as so added). If the applicant or holder gave notice of his wish to make oral representations, the appropriate committee must, after receiving a written summary and any other documents in accordance with Sch 5 para 6(4) (as added), arrange for the applicant or holder to make such representations at a hearing before the committee: Sch 5 para 6(7) (as so added).

18 Ibid Sch 5 para 6(8)(a) (as added: see note 3 supra).

19 Ibid Sch 5 para 6(8)(b) (as added: see note 3 supra).

20 Ibid Sch 5 para 7(1)(a) (as added: see note 3 supra).

21 Ibid Sch 5 para 7(1)(b) (as added: see note 3 supra).

22 Ibid Sch 5 para 7(2)(a) (as added: see note 3 supra).

23 Ibid Sch 5 para 7(2)(b) (as added: see note 3 supra).

24 Ibid Sch 5 para 9(1) (as added: see note 3 supra). Schedule 5 para 9(1) (as added) does not apply where the person has not made any representations in accordance with Sch 5 para 6(4)-(7) (as added) (see note 17 supra) and the decision of the licensing authority was in accordance with the advice of the appropriate committee: Sch 5 para 9(4) (as so added). As to the hearing before the person appointed see PARA 208 post.

25 Ibid Sch 5 para 8(1)(a) (as added: see note 3 supra).

26 Ibid Sch 5 para 8(1)(b) (as added: see note 3 supra).

27 Ibid Sch 5 para 8(1)(c)(i) (as added: see note 3 supra).

28 Ibid Sch 5 para 8(1)(c)(ii) (as added: see note 3 supra).

29 Ibid Sch 5 para 8(1)(c)(iii)(aa) (as added: see note 3 supra).

30 Ibid Sch 5 para 8(1)(c)(iii)(bb) (as added: see note 3 supra).

31 Ibid Sch 5 para 8(1)(c)(iii)(cc) (as added: see note 3 supra).

32 Ibid Sch 5 para 8(1) (as added: see note 3 supra). A notification given under Sch 5 para 8(1) (as added) or Sch 5 para 8(2) (as added) (see the text and notes 33-37 infra) must state the advice of the appropriate committee, if any, and the reasons stated by the committee for any such advice (Sch 5 para 8(3)(a) (as so added)) and the proposals of the licensing authority and the reasons for them (Sch 5 para 8(3)(b) (as so added)).

33 Ibid Sch 5 para 8(2)(a) (as added: see note 3 supra).

34 Ibid Sch 5 para 8(2)(b)(i) (as added: see note 3 supra).

35 Ibid Sch 5 para 8(2)(b)(ii) (as added: see note 3 supra).

36 Ibid Sch 5 para 8(2)(b)(iii) (as added: see note 3 supra).

37 Ibid Sch 5 para 8(2)(b) (as added: see note 3 supra). As to the content of such notification see note 32 supra.

38 Ie under ibid Sch 5 para 8(1) or (2) (as added): see the text and notes 32-37 supra.

39 Ibid Sch 5 para 9(2)(a) (as added: see note 3 supra). As to the hearing before the person appointed see PARA 208 post.

40 Ibid Sch 5 para 9(2)(b) (as added: see note 3 supra).

41 Ibid Sch 5 para 9(3) (as added: see note 3 supra).

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208. Hearing before person appointed.

Where an applicant for a certificate of registration¹ for a homoeopathic medicinal product² or for the renewal of such a certificate³, or the holder⁴ of a certificate of registration for a homoeopathic medicinal product⁵, gives notice⁶ of his wish to appear before or be heard by a person appointed by the licensing authority⁷, the authority must make that appointment⁸ and arrange for the applicant or holder to have an opportunity of appearing before that person⁹.

The applicant or holder must, before the end of the period of three months¹⁰ beginning with the date of his notice, provide the person appointed with a written summary of the oral representations he intends to make¹¹ and any documents on which he wishes to rely in support of those representations¹². If the applicant or holder fails to comply with the time limit, or any extended time limit, he may not appear before or be heard by the person appointed¹³, and the licensing authority must decide whether to confirm or alter its decision¹⁴, to grant or renew the certificate of registration¹⁵, to grant or renew the certificate of registration otherwise than in accordance with the application¹⁶, or to revoke, vary or suspend the certificate of registration¹⁷, as the case may be¹⁸.

At the hearing before the person appointed, both the applicant or holder and the licensing authority may make representations¹⁹ and, if the applicant or holder so requests, the hearing must be in public²⁰. After the hearing the person appointed must provide a report to the licensing authority²¹, and the licensing authority must take this report into account and decide whether to confirm or alter its decision²², to grant or renew the certificate of registration²³, to grant or renew the certificate of registration otherwise than in accordance with the application²⁴, or to revoke, vary or suspend the certificate of registration²⁵, as the case may be²⁶. The licensing authority must then notify the applicant or holder of its decision²⁷ and, if the applicant or holder so requests, provide him with a copy of the report of the person appointed²⁸.

1 For the meaning of 'certificate of registration' see PARA 205 note 1 ante. As to applications for certificates of registration see PARAS 205-206 ante.

2 For the meaning of 'homoeopathic medicinal product' see PARA 205 note 3 ante.

3 Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, regs 5(4), 8(5), 9(2), Sch 5 para 3(a) (regs 5(4), 9(2) substituted, and reg 8(5), Sch 5 added, by SI 2005/2753). As to the renewal of certificates of registration see PARA 206 ante.

4 As to references to the holder of a certificate of registration see PARA 205 note 8 ante.

5 Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, Sch 5 para 3(b) (as added: see note 3 supra).

6 *Ibid* Sch 5 para 9 (as added): see PARA 207 ante.

7 *Ibid* Sch 5 para 3 (as added: see note 3 supra). For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by reg 1(2). See also PARA 206 note 1 ante.

8 *Ibid* Sch 5 para 12(1)(a) (as added: see note 3 supra). The person appointed must not be, or at any time have been, a member of: (1) the Commission on Human Medicines or any of its expert advisory groups; (2) the Medicines Commission formerly established under the Medicines Act 1968 s 2 or any of its committees; or (3) a committee established under s 4 or any sub-committee of such a committee (Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, Sch 5 para 12(2)(a)(i)-(iii) (as so added)); nor may he be an officer or servant of a Minister of the Crown (Medicines (Sch 5 para 12(2)(b) (as so added)).

As to the Commission on Human Medicines and the former Medicines Commission see PARA 13 ante; and as to expert advisory groups see PARA 17 ante. As to Ministers of the Crown see CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARA 354 et seq.

9 Ibid Sch 5 para 12(1)(b) (as added: see note 3 supra). As to the circumstances in which Sch 5 (as added) does not apply see Sch 5 para 4 (as added); and PARA 207 note 3 ante.

10 If the applicant or holder so requests, the person appointed may, after consulting the licensing authority, extend the time limit up to a maximum period of six months beginning with the date of the notice: *ibid* Sch 5 para 12(4) (as added: see note 3 supra). The applicant or holder may not submit any additional written representations or documents once the time limit has expired, except with the permission of the person appointed: Sch 5 para 12(6) (as so added). For the meaning of 'month' see PARA 22 note 15 ante.

11 Ibid Sch 5 para 12(3)(a) (as added: see note 3 supra).

12 Ibid Sch 5 para 12(3)(b) (as added: see note 3 supra).

13 Ibid Sch 5 para 12(5)(a) (as added: see note 3 supra).

14 Ibid Sch 5 para 12(5)(b)(i) (as added: see note 3 supra).

15 Ibid Sch 5 para 12(5)(b)(ii) (as added: see note 3 supra).

16 Ibid Sch 5 para 12(5)(b)(iii) (as added: see note 3 supra).

17 Ibid Sch 5 para 12(5)(b)(iv) (as added: see note 3 supra).

18 Ibid Sch 5 para 12(5)(b) (as added: see note 3 supra).

19 Ibid Sch 5 para 12(7) (as added: see note 3 supra).

20 Ibid Sch 5 para 12(8) (as added: see note 3 supra).

21 Ibid Sch 5 para 12(9)(a) (as added: see note 3 supra).

22 Ibid Sch 5 para 12(9)(b)(i) (as added: see note 3 supra).

23 Ibid Sch 5 para 12(9)(b)(ii) (as added: see note 3 supra).

24 Ibid Sch 5 para 12(9)(b)(iii) (as added: see note 3 supra).

25 Ibid Sch 5 para 12(9)(b)(iv) (as added: see note 3 supra).

26 Ibid Sch 5 para 12(9)(b) (as added: see note 3 supra).

27 Ibid Sch 5 para 12(10)(a) (as added: see note 3 supra).

28 Ibid Sch 5 para 12(10)(b) (as added: see note 3 supra).

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209. Offences.

The following persons¹ are guilty of an offence²:

- 185 (1) any person who, in breach of the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, places a homoeopathic medicinal product on the market³ without holding a certificate of registration⁴ in respect of that product, or otherwise than in accordance with the terms of such a certificate⁵;
- 186 (2) any person who, in the course of a business carried on by him, sells, supplies, manufactures or assembles, or procures the sale, supply, manufacture or assembly of, a homoeopathic medicinal product, or who has in his possession a homoeopathic medicinal product, knowing or having reasonable cause to believe that the product was or is intended to be placed on the market contrary to head (1) above⁷;
- 187 (3) without prejudice to any other sanction which may be available for the enforcement of conditions attaching to certificates of registration, any holder⁸ of a certificate of registration for a homoeopathic medicinal product who contravenes any condition of the certificate⁹;
- 188 (4) any person who is or, immediately before its revocation or suspension, was the holder of a certificate of registration who fails to comply with a notice¹⁰ given to him requiring the withdrawal from the market of a product¹¹;
- 189 (5) any holder of a certificate of registration who fails promptly to:
 - 21 23. (a) take any steps¹² reasonably necessary to take account of technical and scientific progress for the purposes of making any changes or amendments¹³; or
 24. (b) introduce any changes or make any amendments that may be required¹⁴; or
 25. (c) provide information¹⁵ to the licensing authority¹⁶; or
 26. (d) submit any application¹⁷ to the licensing authority to make any changes or variation¹⁸;
- 22 190 (6) any holder of a certificate of registration who fails to forward¹⁹ to the licensing authority any data requested by the authority²⁰;
- 191 (7) any person who is the holder of a certificate of registration who fails, not less than two months before an interruption in the placing on the market of the product to which the certificate relates, to notify the licensing authority that the product is to cease to be placed on the market²¹;
- 192 (8) any person who is the holder of a certificate of registration who fails to ensure²² appropriate and continued supplies²³;
- 193 (9) any person who in the course of an application for the grant, renewal or variation of a certificate of registration²⁴ for a homoeopathic medicinal product:
 - 23 27. (a) fails to provide to the licensing authority any information²⁵ which is relevant to an evaluation of the quality of the homoeopathic medicinal product²⁶; or
 28. (b) provides to the licensing authority any information which is relevant to an evaluation of the quality of the homoeopathic medicinal product but which is false or misleading in a material particular²⁷;

24

- 194 (10) any person who is responsible for placing a homoeopathic medicinal product on the market²⁸ or is the holder of a certificate of registration for a homoeopathic medicinal product²⁹ who provides to the licensing authority any information which is relevant to an evaluation of the quality of the homoeopathic medicinal product but which is false or misleading in a material particular³⁰;
- 195 (11) any holder of a certificate of registration who sells or supplies or procures the sale or supply of a homoeopathic medicinal product to which the certificate of registration relates, the labelling of which, or any package insert accompanying which, does not comply with the applicable requirements³¹;
- 196 (12) any person, other than the holder of a certificate of registration for a homoeopathic medicinal product, who in the course of a business carried on by him sells or supplies or procures the sale or supply of a homoeopathic medicinal product knowing, or having reasonable cause to believe, that the labelling of the product, or any package insert accompanying the product, does not comply with the applicable requirements³².

Where the holder of a certificate of registration is charged with an offence in respect of anything which has been manufactured or assembled to his order by another person and had been so manufactured or assembled as not to comply with the provisions of that certificate, it is a defence for him to prove³³ that he had communicated the provisions relating to the certificate of registration to that other person³⁴ and that he did not know, and could not by the exercise of reasonable care have known, that those provisions had not been complied with³⁵.

A person does not commit an offence under heads (7) to (10) above if he took all reasonable precautions and exercised all due diligence to avoid the commission of that offence³⁶. Where evidence is adduced which is sufficient to raise an issue with respect to that defence, the court or jury must assume that the defence is satisfied unless the prosecution proves beyond reasonable doubt that it is not³⁷.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 Any person guilty of any such offence is liable on summary conviction to a fine not exceeding the statutory maximum, or on conviction on indictment to a fine or imprisonment for a term not exceeding two years or both: Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 7A(3), Sch 6 para 12 (reg 7A, Sch 6 added by SI 2005/2753). As to the statutory maximum see PARA 32 note 3 ante.

3 As to placing a product on the market see PARA 205 note 2 ante. For the meaning of 'homoeopathic medicinal product' see PARA 205 note 3 ante.

4 For the meaning of 'certificate of registration' see PARA 205 note 1 ante.

5 Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, Sch 6 para 1 (as added: see note 2 supra).

6 For the meaning of 'manufacture' see PARA 7 note 2 ante; and for the meaning of 'assembly' see PARA 6 note 8 ante (definitions applied by *ibid* reg 1(2)).

7 *Ibid* Sch 6 para 2 (as added: see note 2 supra). As to a defence to this offence see the text and notes 33-35 *infra*.

8 As to references to the holder of a certificate of registration see PARA 205 note 8 ante.

9 Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, Sch 6 para 3 (as added: see note 2 supra).

10 *Ie* under *ibid* reg 10 (as amended): see PARA 210 *post*.

11 *Ibid* Sch 6 para 4 (as added: see note 2 supra).

12 *Ie* as required by EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 23.

13 Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, Sch 6 para 5(a) (as added: see note 2 supra).

14 Ibid Sch 6 para 5(b) (as added: see note 2 supra). The changes or amendments are those required in accordance with EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 23 or Annex I Pt I paras 3.2(9), 3.2.1.2(c), 3.2.2.4(c).

15 Ie as required by ibid art 23 (third or fourth paragraph) or art 23a (first paragraph).

16 Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, Sch 6 para 5(c) (as added: see note 2 supra). For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by reg 1(2). See also PARA 206 note 1 ante.

17 Ie as required by EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 23.

18 Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, Sch 6 para 5(d) (as added: see note 2 supra).

19 Ie pursuant to EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 23 (final paragraph) or art 23a (final paragraph): (1) where the licensing authority have served a written notice on the holder under the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 7A(4) (as added) (see PARA 205 ante) in relation to the request, within the time specified in that notice (Sch 6 para 6(a) (as added: see note 2 supra)); (2) where there is no such notice, promptly (Sch 6 para 6(b) (as so added)).

20 Ibid Sch 6 para 6 (as added: see note 2 supra).

21 Ibid Sch 6 para 7 (as added: see note 2 supra). This provision is expressed to be subject to Sch 6 para 14 (as added): see the text to notes 36-37 infra.

22 Ie pursuant to EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 81 (second paragraph).

23 Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, Sch 6 para 8 (as added: see note 2 supra). This provision is expressed to be subject to Sch 6 para 14 (as added): see the text to notes 36-37 infra.

24 As to applications for the grant, renewal or variation of a certificate of registration see PARA 206 ante.

25 Ie as required by EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 15.

26 Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, Sch 6 para 9(1)(a) (as added: see note 2 supra). This provision is expressed to be subject to Sch 6 para 14 (as added): see the text to notes 36-37 infra.

27 Ibid Sch 6 para 9(1)(b) (as added: see note 2 supra). This provision is expressed to be subject to Sch 6 para 14 (as added): see the text to notes 36-37 infra.

28 Ibid Sch 6 para 9(2)(a) (as added: see note 2 supra).

29 Ibid Sch 6 para 9(2)(b) (as added: see note 2 supra).

30 Ibid Sch 6 para 9(2) (as added: see note 2 supra). This provision is expressed to be subject to Sch 6 para 14 (as added): see the text to notes 36-37 infra.

31 Ibid Sch 6 para 10 (as added: see note 2 supra). The applicable requirements are those of EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) Title V.

32 Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, Sch 6 para 11 (as added: see note 2 supra). The applicable requirements are those of EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) Title V.

33 As to the standard of proof see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(3) (2006 Reissue) PARA 1372.

34 Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, Sch 6 para 13(a) (as added: see note 2 supra).

- 35 Ibid Sch 6 para 13(b) (as added: see note 2 supra).
- 36 Ibid Sch 6 para 14(1) (as added: see note 2 supra).
- 37 Ibid Sch 6 para 14(2) (as added: see note 2 supra). See also note 33 supra.

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210. Withdrawal from the market.

The holder of a certificate of registration¹ must withdraw from the market all products to which that certificate relates within the time and for the period specified in any written² notice³ issued by the licensing authority⁴. The licensing authority may, and where appropriate must, issue such a notice, subject to and in accordance with the provisions of the Directive⁵ on the Community code relating to medicinal products for human use⁶. The licensing authority may order the holder of the certificate of registration to withdraw from the market specified batches only of a product to which a notice applies⁷.

¹ For the meaning of 'certificate of registration' see PARA 205 note 1 ante. As to references to the holder of a certificate of registration see PARA 205 note 8 ante.

² For the meaning of 'written' see PARA 21 note 4 ante; definition applied by the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 1(2).

³ The notice must be served on the holder of the relevant certificate and must specify the grounds for the issue of the notice: *ibid* reg 10(4). As to the service of notices see PARA 37 note 8 ante; provision applied by reg 19, Sch 4.

⁴ *Ibid* reg 10(1). For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by reg 1(2). See also PARA 206 note 1 ante. As to the keeping by the holder of a certificate of such documents as will facilitate the withdrawal or recall from sale or supply of any homoeopathic medicinal product see reg 7A(2) (as added); and PARA 205 ante.

⁵ *Ie* EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) (as amended).

⁶ Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 10(2) (substituted by SI 2005/2753).

⁷ Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 10(3).

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211. Fees.

No fee is payable in connection with an application for the grant or variation of a certificate of registration¹ where the application is made at the specific written² invitation of the licensing authority³. Subject to this exception, fees are payable by an applicant in respect of an application for the grant of a certificate of registration⁴ and in connection with an application for a variation of a certificate of registration⁵. Any such fee is payable to the licensing authority at the time the application for grant or variation of the certificate of registration is made⁶. In certain circumstances⁷ the licensing authority must refund or waive payment of any fee or part of a fee in respect of an application for a certificate of registration⁸. Fees are also payable in connection with applications to the licensing authority for regulatory assistance with obtaining a certificate of registration in another EEA state or states⁹.

The holder of a certificate of registration¹⁰ must pay a fee of £15 in respect of each fee period¹¹ during any part of which the certificate is in force¹², except that no fee is payable in respect of the fee period during which a certificate of registration is first granted¹³. The fee is payable to the licensing authority on the first day of the fee period to which it relates¹⁴.

All unpaid sums due by way of, or on account of, any fees payable are recoverable as debts due to the Crown¹⁵.

1 For the meaning of 'certificate of registration' see PARA 205 note 1 ante. As to applications for the grant or variation of a certificate see PARAS 205-208 ante.

2 For the meaning of 'written' see PARA 21 note 4 ante; definition applied by the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 1(2).

3 Ibid reg 12. For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by reg 1(2). See also PARA 206 note 1 ante.

4 See ibid reg 13(1) (renumbered by SI 2005/2753). As to the fees payable see the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, Sch 2 (amended by SI 2005/2753).

5 See the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 14(1), (2). As to the fees payable see reg 14(1)(a), (b), 2(a), (b) (reg 14(1)(b) amended by SI 2003/625; and the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 14(2)(b) amended by SI 2004/666).

6 Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 16(1) (amended by SI 2005/2753).

7 Where an application for the grant of a certificate of registration is withdrawn before determination by the licensing authority, the following percentage of the fee otherwise payable in connection with that application must be refunded or, if it has not yet been paid, waived: (1) if the application has been received but no medical, scientific or pharmaceutical assessment of it has begun, 90% (Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 17, Sch 3 para 1(a)); (2) if medical, scientific or pharmaceutical assessment has begun but has not been completed, 50% (Sch 3 para 1(b)). However, if an application for the grant of a certificate is withdrawn after medical, scientific and pharmaceutical assessment has been completed or following consideration of that application by the Advisory Board on the Registration of Homoeopathic Products, no refund or waiver of the fee payable in connection with that application may be made: Sch 3 para 2. As to the Board see PARA 204 ante.

8 Ibid reg 17.

9 See *ibid* reg 13(2) (regs 13(2), 16(1A), Sch 2A added by SI 2005/2753). As to when such fees are payable see the Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 16(1A) (as so added). As to the fees payable see Sch 2A (as so added). For the meaning of 'EEA state' see PARA 207 note 3 ante.

10 As to references to the holder of a certificate of registration see PARA 205 note 8 ante.

11 'Fee period' means the period beginning with the first day of April in any year and ending with the last day of March in the following year: Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 15(3).

12 *Ibid* reg 15(1) (amended by SI 2004/666).

13 Medicines (Homoeopathic Medicinal Products for Human Use) Regulations 1994, SI 1994/105, reg 15(2).

14 *Ibid* reg 16(2).

15 *Ibid* reg 18. As to the enforcement of court orders in respect of debts due to the Crown see CONTEMPT OF COURT vol 9(1) (Reissue) PARA 487; CIVIL PROCEDURE vol 12 (2009) PARA 1239.

UPDATE

211 Fees

TEXT AND NOTES--As to the fee for a person appointed hearing see SI 1994/105 reg 15A (added by SI 2009/389).

NOTE 4--SI 1994/105 Sch 2 further amended: SI 2007/803, SI 2008/552, SI 2009/389.

NOTE 5--SI 1994/105 reg 14(2) further amended: SI 2007/803. SI 1994/105 reg 14(1), (2) further amended: SI 2008/552, SI 2009/389.

NOTE 9--SI 1994/105 Sch 2A amended: SI 2007/803, SI 2008/552, SI 2009/389.

NOTE 12--SI 1994/105 reg 15(1) amended: SI 2007/803, SI 2008/552, SI 2009/389.

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(ii) Veterinary Medicinal Products

A. IN GENERAL

212. Homoeopathic veterinary medicinal products.

The regulations¹ relating to the registration of homoeopathic veterinary medicinal products² apply to homoeopathic veterinary medicinal products to which the provisions of the Homoeopathics Directive apply and which satisfy all of the conditions specified³ in that Directive⁴. However, the regulations do not apply to homoeopathic veterinary medicinal products that were marketed⁵ in the United Kingdom⁶ for the first time before 31 March 1997⁷.

The marketing of products is restricted unless the product concerned is registered⁸; and the manufacture and importation of products is restricted unless the product concerned is registered and the person wishing to effect the manufacture or importation holds an appropriate authorisation⁹. There are also certain restrictions as to the exportation of products¹⁰.

Various provisions of the Medicines Act 1968, instruments made under those provisions and any other provision of the Act which relates to those provisions, apply in relation to products to which the regulations apply, and those provisions and instruments apply in relation to those products as if they were medicinal products¹¹ to which the Act applies, whether or not they would otherwise be so¹².

1 le the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322.

2 'Homoeopathic veterinary medicinal product' has the meaning given by the Homoeopathics Directive art 1: Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 2(1). 'The Homoeopathics Directive' means EC Council Directive 92/74 (OJ L297, 13.10.1992, p 12) widening the scope of EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) on the approximation of the provisions laid down by law, regulation or administrative action relating to veterinary medicinal products and laying down additional provisions on homoeopathic veterinary medicinal products as adapted by the EEA Agreement; and 'EEA Agreement' means the Agreement on the European Economic Area (Oporto, 2 May 1992; EC 7 (1992); Cm 2183) as adjusted by the Protocol (Brussels, 17 March 1993; EC 2 (1993); Cm 2183) and as amended by the Decision of the EEA Joint Committee No 7/94: Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 2(1).

3 le specified in the Homoeopathics Directive art 7.1.

4 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 3(1). 'Product' means a product to which the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, apply by virtue of reg 3(1): reg 2(1).

5 'Market' has the same meaning as in the Homoeopathics Directive: Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 2(2), Sch 1 Pt I.

6 For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

7 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 3(2).

8 As to registration see PARA 214 et seq post.

9 As to authorisations see PARA 222 et seq post.

10 See PARA 222 post.

11 For the meaning of 'medicinal product' see PARA 7 ante; definition applied by the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 34(1), Sch 5.

12 Ibid reg 34(1), Sch 5. The provisions of the Medicines Act 1968 referred to in the text are: ss 51-58, 59-61 (provisions as to sale or supply of medicinal products) (see PARAS 133-140, 142-144 ante), s 67 (offences) (see PARA 178 ante), ss 92-95, 97 (promotion of sales of medicinal products) (see PARAS 157-161, 166 ante), s 107 (validity of decisions and proceedings relating thereto) (see PARA 79 ante), ss 108, 111-115, Sch 3 (enforcement) (see PARAS 168-172 ante), s 119 (protection for officers of enforcement authorities) (see PARA 175 ante), ss 121-126 (provisions relating to offences) (see PARAS 179-181, 183-184 ante), s 127 (service of documents) (see PARA 37 note 8 ante), s 129 (orders and regulations) (see PARA 5 ante), s 132 (general interpretation provisions), and s 133(2) (general provisions as to operation of the Act) (see PARA 10 ante).

UPDATE

212-229 Veterinary Medicinal Products

Veterinary Medicinal Products Regulations 1997, SI 1997/322 and Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. Provision as to veterinary medicinal products is now made by the Veterinary Medicines Regulations 2009, SI 2009/2297: see PARAS 34A-34D.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(13) HOMOEOPATHIC MEDICINAL PRODUCTS/(ii) Veterinary Medicinal Products/A. IN GENERAL/213. Confidentiality.

213. Confidentiality.

Except in the performance of his duty, no person may disclose any information in respect of any manufacturing¹ process or trade secret obtained by him in premises which he has entered by virtue of the regulations², or any information obtained by him or furnished to him in pursuance of the regulations³.

1 'Manufacture' has the same meaning as in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) on the approximation of the laws of the member states relating to veterinary medicinal products as amended by EC Council Directive 90/676 (OJ L373, 31.12.1990, p 26) and EC Council Directive 93/40 (OJ L214, 24.8.1993, p 31) as widened by the Homoeopathics Directive and as adapted by the EEA Agreement; and 'manufacture' includes the activities specified in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 24.2 (first paragraph) but does not include the activities specified in art 24.2 (second paragraph): Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 1(2), 2(1), (3), Sch 1 Pt I. Any reference to a provision of EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) means the specified provision of that Directive as such provision applies to a product by virtue of the Homoeopathics Directive art 3, 4 or 7.3: Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 2(4). For the meanings of 'the Homoeopathics Directive' and 'EEA Agreement' see PARA 212 note 2 ante.

2 le the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322.

3 Ibid reg 28. It is an offence to contravene or fail to comply with this provision: see reg 32(1); and PARA 229 post.

UPDATE

212-229 Veterinary Medicinal Products

Veterinary Medicinal Products Regulations 1997, SI 1997/322 and Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. Provision as to veterinary medicinal products is now made by the Veterinary Medicines Regulations 2009, SI 2009/2297: see PARAS 34A-34D.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(13) HOMOEOPATHIC MEDICINAL PRODUCTS/(ii) Veterinary Medicinal Products/B. REGISTRATION/214. Restrictions on the marketing of products.

B. REGISTRATION

214. Restrictions on the marketing of products.

No person¹ may market² a product³ on or after 1 September 1997 unless the product is registered⁴ and complies with the article 8 dossier⁵ relating to it⁶. The person responsible for marketing⁷ a registered product must comply with the applicable requirements⁸ in connection with such product⁹. No person may market a registered product unless the labelling¹⁰ and any package¹¹ insert complies with the applicable requirements¹².

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 As to the meaning of 'market' see PARA 212 note 5 ante.

3 For the meaning of 'product' see PARA 212 note 4 ante.

4 For the meaning of 'registered' see PARA 215 note 5 post.

5 For the meaning of 'article 8 dossier' see PARA 217 note 1 post.

6 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 18. It is an offence to contravene or fail to comply with this provision: see reg 32(1); and PARA 229 post.

7 'Person responsible for marketing' has the same meaning as in the Homoeopathics Directive: Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 2(2), Sch 1 Pt I. For the meaning of 'the Homoeopathics Directive' see PARA 212 note 2 ante.

8 I.e. the requirements of EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) arts 14, 35, 42.2.

9 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 19. It is an offence to contravene or fail to comply with this provision: see reg 32(2); and PARA 229 post.

10 For the meaning of 'labelling' see PARA 152 note 4 ante; definition applied by *ibid* reg 34(1), Sch 5.

11 For the meaning of 'package' see PARA 152 note 4 ante; definition applied by *ibid* reg 34(1), Sch 5.

12 *Ibid* reg 21. The applicable requirements are those specified in the Homoeopathics Directive arts 2.2, 7.2: Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 21. For the meaning of 'the Homoeopathics Directive' see PARA 212 note 2 ante. It is an offence to contravene or fail to comply with this provision: see the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 32(2); and PARA 229 post. Anything which, in accordance with the Trade Descriptions Act 1968 (see SALE OF GOODS AND SUPPLY OF SERVICES vol 41 (2005 Reissue) PARA 475 et seq) constitutes the application of a trade description to a registered product is deemed not to be a trade description if it is applied to such product in accordance with the requirements of the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 21: reg 35(1).

UPDATE

212-229 Veterinary Medicinal Products

Veterinary Medicinal Products Regulations 1997, SI 1997/322 and Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products.

Provision as to veterinary medicinal products is now made by the Veterinary Medicines Regulations 2009, SI 2009/2297: see PARAS 34A-34D.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(13) HOMOEOPATHIC MEDICINAL PRODUCTS/(ii) Veterinary Medicinal Products/B. REGISTRATION/215. Registration of products.

215. Registration of products.

A person responsible for marketing¹, or intending to market² a product³, may apply to the ministers⁴ to register the product⁵. Such an application must be made in writing⁶, in the English language, signed by or on behalf of the applicant, and must contain the name and address of the applicant and be accompanied by the article 8 documents⁷ relating to the product⁸. The application may relate to a series of products derived from the same homoeopathic stock or stocks⁹.

Where an application is made, the ministers must examine it in accordance with the criteria and rules of procedure¹⁰ relating to such applications¹¹, and taking account of the specified¹² matters¹³. Following the examination of an application to register a product, the ministers must register it¹⁴ unless, in their opinion, an article 11 ground¹⁵ has been established in connection with that product or application¹⁶. On registering a product, the ministers must give it a registration number¹⁷, determine whether there is a need to exercise or further exercise the powers¹⁸ concerning the conditions as to the sale or supply of the product¹⁹, and publish²⁰ details of the registration²¹. Where the ministers refuse to register a product, they must notify²² the applicant²³.

Certain statutory provisions do not apply to registered products²⁴.

1 As to the meaning of 'person responsible for marketing' see PARA 214 note 7 ante.

2 As to the meaning of 'market' see PARA 212 note 5 ante.

3 For the meaning of 'product' see PARA 212 note 4 ante.

4 For these purposes, 'the ministers' means the Secretary of State, the Department of Agriculture for Northern Ireland and the Department of Health and Social Services for Northern Ireland: Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 2(1) (definition amended by SI 1999/3142); Ministry of Agriculture, Fisheries and Food (Dissolution) Order 2002, SI 2002/794. The regulations refer to the Minister of Agriculture, Fisheries and Food and the Secretary of State concerned with health in England, but the functions of the Minister of Agriculture, Fisheries and Food have been transferred to the Secretary of State. As to the Secretary of State see PARA 3 note 3 ante. Any function conferred on the ministers may be performed by any one of those ministers acting alone or by any two or more of them acting jointly: Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 2(5).

5 Ibid reg 4(1). 'Registered' means registered by the ministers under the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322: reg 2(1). As to fees payable in respect of such applications see the Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750.

6 For the meaning of 'writing' see PARA 21 note 6 ante; definition applied by the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 34(1), Sch 5.

7 'Article 8 documents' means the particulars and documents specified in the Homoeopathics Directive art 8: Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 2(1). For the meaning of 'the Homoeopathics Directive' see PARA 212 note 2 ante.

8 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 4(2).

9 Ibid reg 4(3). 'Homoeopathic stock' has the same meaning as in the Homoeopathics Directive: Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 2(2), Sch 1 Pt I.

- 10 Ie specified in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) arts 8-12, with the exception, in the case of art 11, of the proof of therapeutic effect: Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 5(a).
- 11 Ibid reg 5(a).
- 12 Ie specified in the Homoeopathics Directive art 6.1.
- 13 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 5(b).
- 14 Ie in accordance with the provisions of EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 15.
- 15 'Article 11 ground' means a ground specified in ibid art 11 (first paragraph sub-paragraph 1 or 3), or art 11 (second paragraph): Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 2(1).
- 16 Ibid reg 6(1). This provision is expressed to be subject to regs 11, 12: see PARAS 220-221 post.
- 17 Ibid reg 6(2)(a).
- 18 Ie conferred by the Medicines Act 1968 s 51 (see PARA 133 ante), s 57 (as amended) (see PARAS 137, 139 ante), s 58 (as amended) (see PARA 140 ante).
- 19 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 6(2)(b).
- 20 Ie in accordance with the provisions in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 40 (second paragraph).
- 21 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 6(2)(c).
- 22 Ie in accordance with the provisions of EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 40 (first paragraph).
- 23 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 6(3).
- 24 See ibid regs 35(2), 36. The provisions are: the Consumer Protection Act 1987 Pt II (ss 10-19) (consumer safety) (see SALE OF GOODS AND SUPPLY OF SERVICES vol 41 (2005 Reissue) PARA 528 et seq); the Importation of Animal Products and Poultry Products Order 1980, SI 1980/14 (see ANIMALS vol 2 (2008) PARAS 1081, 1084, 1109); and the Control of Pesticides Regulations 1986, SI 1986/1510 (see AGRICULTURAL PRODUCTION AND MARKETING vol 1 (2008) PARA 1037).

UPDATE

212-229 Veterinary Medicinal Products

Veterinary Medicinal Products Regulations 1997, SI 1997/322 and Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. Provision as to veterinary medicinal products is now made by the Veterinary Medicines Regulations 2009, SI 2009/2297: see PARAS 34A-34D.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(13) HOMOEOPATHIC MEDICINAL PRODUCTS/(ii) Veterinary Medicinal Products/B. REGISTRATION/216. Renewal of registrations.

216. Renewal of registrations.

The registration of a product¹ may be renewed on the application of the person responsible for marketing it². Such an application must be made to the ministers³ at least three months before the expiry of the registration relating to the product and must be accompanied by an article 15 dossier⁴ relating to it⁵. Following the examination of the application, the ministers must renew the registration unless, in their opinion, an article 11 ground⁶ has been established in connection with the product⁷. Where the ministers refuse to renew a registration, they must notify⁸ the applicant⁹.

1 For the meaning of 'product' see PARA 212 note 4 ante. As to the registration of products see PARA 215 ante.

2 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 7(1). As to the meaning of 'person responsible for marketing' see PARA 214 note 7 ante. As to fees payable in respect of such applications see the Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750.

3 For the meaning of 'the ministers' see PARA 215 note 4 ante.

4 'Article 15 dossier' means a dossier of the type specified in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 15.1: Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 2(1).

5 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, 7(2).

6 For the meaning of 'article 11 ground' see PARA 215 note 15 ante.

7 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 7(3). This provision is expressed to be subject to regs 11, 12: see PARAS 220-221 post.

8 Ie in accordance with the provisions of EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 40 (first paragraph).

9 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 7(4).

UPDATE

212-229 Veterinary Medicinal Products

Veterinary Medicinal Products Regulations 1997, SI 1997/322 and Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. Provision as to veterinary medicinal products is now made by the Veterinary Medicines Regulations 2009, SI 2009/2297: see PARAS 34A-34D.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(13) HOMOEOPATHIC MEDICINAL PRODUCTS/(ii) Veterinary Medicinal Products/B. REGISTRATION/217. Alteration of dossiers relating to registered products.

217. Alteration of dossiers relating to registered products.

An application for authorisation to make an alteration to an article 8 dossier¹ relating to a registered² product may be made to the ministers³ by the person responsible for marketing⁴ the product and must be accompanied by full details of the proposed alteration⁵. Where such an application is made, the ministers must authorise the proposed alteration unless, in their opinion, the making of the alteration would result in an article 11 ground⁶ being established in connection with that product⁷. Where the ministers authorise a proposed alteration of an article 8 dossier, they must make any necessary amendments to the registration⁸.

1 'Article 8 dossier' means the article 8 documents on which a registration relating to a product is based, and: (1) where the registration relating to a product has been renewed in accordance with the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 7 (see PARA 216 ante), the expression means the article 8 documents as updated by the article 15 dossier provided in connection with the renewal application; and (2) where the documents have been altered in accordance with reg 8, the expression means the article 8 documents as so altered: reg 2(1). For the meaning of 'article 8 documents' see PARA 215 note 7 ante; and for the meaning of 'article 15 dossier' see PARA 216 note 4 ante. For the meaning of 'product' see PARA 212 note 4 ante.

2 For the meaning of 'registered' see PARA 215 note 5 ante.

3 For the meaning of 'the ministers' see PARA 215 note 4 ante.

4 As to the meaning of 'person responsible for marketing' see PARA 214 note 7 ante.

5 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 8(1). As to fees payable in respect of applications see the Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750 (amended by SI 2004/3081).

6 For the meaning of 'article 11 ground' see PARA 215 note 15 ante.

7 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 8(2).

8 Ibid reg 8(3). As to the registration see para 215 ante.

UPDATE

212-229 Veterinary Medicinal Products

Veterinary Medicinal Products Regulations 1997, SI 1997/322 and Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. Provision as to veterinary medicinal products is now made by the Veterinary Medicines Regulations 2009, SI 2009/2297: see PARAS 34A-34D.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(13) HOMOEOPATHIC MEDICINAL PRODUCTS/(ii) Veterinary Medicinal Products/B. REGISTRATION/218. Suspension and revocation of registrations.

218. Suspension and revocation of registrations.

The ministers¹ must suspend or revoke the registration of a registered² product³ if in their opinion a specified⁴ ground has been established in connection with the product⁵; and the ministers may suspend or revoke the registration of a registered product if in their opinion a different specified⁶ ground has been established in connection with the product⁷. Where the ministers suspend or revoke the registration of a registered product under either of these provisions, they must notify⁸ the person responsible for marketing⁹ the product and must comply with the publication requirements¹⁰.

1 For the meaning of 'the ministers' see PARA 215 note 4 ante.

2 For the meaning of 'registered' see PARA 215 note 5 ante.

3 For the meaning of 'product' see PARA 212 note 4 ante.

4 I.e. specified in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 36 (first paragraph sub-paragraph 1 or 3).

5 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 9(1). This provision is expressed to be subject to regs 11, 12: see PARAS 220-221 post.

6 I.e. specified in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 36 (last paragraph).

7 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 9(2).

8 I.e. in accordance with the provisions of EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 40 (first paragraph).

9 As to the meaning of 'person responsible for marketing' see PARA 214 note 7 ante.

10 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 9(3). The publication requirements are those of EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 40 (second paragraph).

UPDATE

212-229 Veterinary Medicinal Products

Veterinary Medicinal Products Regulations 1997, SI 1997/322 and Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. Provision as to veterinary medicinal products is now made by the Veterinary Medicines Regulations 2009, SI 2009/2297: see PARAS 34A-34D.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(13) HOMOEOPATHIC MEDICINAL PRODUCTS/(ii) Veterinary Medicinal Products/B. REGISTRATION/219. Prohibition and withdrawal notices.

219. Prohibition and withdrawal notices.

If in the opinion of the ministers¹ a specified² ground has been established in connection with a product³, they must serve a notice⁴ on the person responsible for marketing⁵ the product requiring that person to stop supplying the product and to withdraw it from the market⁶. A notice so served may relate to the registered⁷ product in general or to a specific batch⁸ of the product as specified in the notice⁹.

A person on whom a notice is served in relation to the supply of a product or its withdrawal from the market, or the supply or withdrawal of particular batches, must comply with the terms of the notice¹⁰.

1 For the meaning of 'the ministers' see PARA 215 note 4 ante.

2 Ie specified in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 37.1 para (a), (c) or (e).

3 For the meaning of 'product' see PARA 212 note 4 ante.

4 'Notice' means notice in writing: Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 2(1). For the meaning of 'writing' see PARA 21 note 6 ante; definition applied by reg 34(1), Sch 5. As to the service of notices see PARA 37 note 8 ante; provision applied by reg 34(1), Sch 5.

5 As to the meaning of 'person responsible for marketing' see PARA 214 note 7 ante.

6 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 10(1). This provision is expressed to be subject to regs 11, 12: see PARAS 220-221 post. As to the meaning of 'market' see PARA 212 note 5 ante.

7 For the meaning of 'registered' see PARA 215 note 5 ante.

8 'Batch' has the same meaning as in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1): Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 2(3), Sch 1 Pt II.

9 Ibid reg 10(2).

10 See ibid reg 20. It is an offence to contravene or fail to comply with this provision: see reg 32(1); and PARA 229 post.

UPDATE

212-229 Veterinary Medicinal Products

Veterinary Medicinal Products Regulations 1997, SI 1997/322 and Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. Provision as to veterinary medicinal products is now made by the Veterinary Medicines Regulations 2009, SI 2009/2297: see PARAS 34A-34D.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(13) HOMOEOPATHIC MEDICINAL PRODUCTS/(ii) Veterinary Medicinal Products/B. REGISTRATION/220. Action on grounds relating to safety or quality.

220. Action on grounds relating to safety or quality.

If the ministers¹ propose, on a ground that concerns the safety or quality of the product² in question, to:

- 197 (1) refuse a registration³;
- 198 (2) refuse to renew a registration⁴;
- 199 (3) suspend or revoke a registration⁵; or
- 200 (4) serve a notice⁶ in relation to the supply of the product or its withdrawal from the market⁷,

the following provisions have effect⁸.

Except where the ministers consider that it is necessary to take action of the type specified in head (3) or (4) above urgently in order to protect human or animal⁹ health or the environment¹⁰, where the ministers propose to act in a manner specified in heads (1) to (4) above they must not act in that manner except after consultation with the Advisory Board on the Registration of Homoeopathic Products¹¹. Where the Board is consulted, it must report to the ministers its advice, and the reasons for its advice¹². After the Board has reported to the ministers, the ministers, taking account of that report, may finally determine not to take the proposed action¹³, or provisionally determine to take that action¹⁴. Where the ministers provisionally determine to take the proposed action, they must not act in that manner except after consultation with the Commission on Human Medicines¹⁵.

Where the Commission is consulted, and it has reason to think that:

- 201 (a) on a ground¹⁶ that concerns the safety or quality of the product, it may have to advise the ministers that the registration of the product should be refused, or that it should not be registered¹⁷ unless the registration is made subject to certain specific obligations¹⁸;
- 202 (b) on a ground¹⁹ that concerns the safety or quality of the product, it may have to advise the ministers that registration of the product should not be renewed, or that it should not be renewed unless the renewed registration is made subject to certain specific obligations²⁰;
- 203 (c) on a ground²¹ that concerns the safety or quality of the product, it may have to advise the ministers that the registration of the product ought to be suspended or revoked²²; or
- 204 (d) on a ground²³ that concerns the safety or quality of the product, it may have to advise the ministers that a notice²⁴ should be served²⁵,

the Commission must, before giving that advice to the ministers, serve a notice²⁶ on the applicant, or the person responsible for marketing²⁷, as the case may be²⁸. Where the Commission is consulted, it must report to the ministers its findings and advice and the reasons for its advice, and, in a case where a notice has been served²⁹, it must make that report after considering any written representation made to it on or before the response date specified in that notice³⁰. After the Commission has reported to the ministers, they must take that report into account in finally determining whether to take the proposed action³¹.

It is a duty of both the Board and the Commission to consider any matter referred to them by the ministers in accordance with these provisions, and to report their findings and advice in connection with any such matter, and their reasons for giving such advice, to the ministers³².

1 For the meaning of 'the ministers' see PARA 215 note 4 ante.

2 For the meaning of 'product' see PARA 212 note 4 ante.

3 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 11(1)(a). As to registration see PARA 215 ante.

4 Ibid reg 11(1)(b). As to renewal of registration see PARA 216 ante.

5 Ibid reg 11(1)(c). As to suspension and revocation of registration see PARA 218 ante.

6 Ie under ibid reg 10(1): see PARA 219 ante. For the meaning of 'notice' see PARA 219 note 4 ante.

7 Ibid reg 11(1)(d). As to the meaning of 'market' see PARA 212 note 5 ante.

8 Ibid reg 11(1). Regulation 11(1) does not apply where the ministers propose to refuse to register a product, or to refuse to renew or to suspend or revoke its registration on the ground specified in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 11 (first paragraph sub-paragraph 3): Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 11(2).

9 For the meaning of 'animal' see PARA 3 note 7 ante; definition applied by ibid reg 34(1), Sch 5.

10 Ibid reg 11(1), Sch 2 para 8(1). Where urgent action is taken by the ministers, they must consult the Advisory Board on the Registration of Homoeopathic Products within three months of taking the action (reg 2(1), Sch 2 para 8(2)(a)), and comply with such of the provisions of Sch 2 as are applicable in the circumstances to that action (Sch 2 para 8(2)(b)). As to the Board see PARA 204 ante.

11 Ibid Sch 2 para 1.

12 Ibid Sch 2 para 2.

13 Ibid Sch 2 para 3(a).

14 Ibid Sch 2 para 3(b).

15 Ibid reg 34(1), Sch 2 para 4, Sch 5. The Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, refer to the Medicines Commission, which is now replaced by the Commission on Human Medicines: see PARA 13 note 1 ante. As to the constitution of the Commission see PARA 13 ante.

16 Ie under ibid reg 11(1): see the text to notes 1-8 supra.

17 For the meaning of 'registered' see PARA 215 note 5 ante.

18 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, Sch 2 para 5(1)(a).

19 Ie under ibid reg 11(1): see the text to notes 1-8 supra.

20 Ibid Sch 2 para 5(1)(b).

21 Ie specified in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 36.

22 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, Sch 2 para 5(1)(c).

23 Ie specified in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 37.1.

24 Ie under the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 10(1): see PARA 219 ante.

25 Ibid Sch 2 para 5(1)(d).

26 Any such notice served must: (1) notify the person on whom it is served of the advice that the Commission is minded to give to the ministers (ibid Sch 2 para 5(2)(a)); (2) state the reasons why the Commission is minded to give that advice (Sch 2 para 5(2)(b)); and (3) specify that, on or before the response date specified in the notice, the person on whom the notice is served may make written representations to the Commission with respect to the advice or reasons (Sch 2 para 5(2)(c)). For the meaning of 'person' see PARA 21 note 7 ante. For the meaning of 'written' see PARA 21 note 4 ante; definition applied by reg 34(1), Sch 5. As to the service of notices see PARA 37 note 8 ante; provision applied by reg 34(1), Sch 5.

27 As to the meaning of 'person responsible for marketing' see PARA 214 note 7 ante.

28 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, Sch 2 para 5(1).

29 *Ie* under ibid Sch 2 para 5(1): see the text to notes 26-28 *supra*.

30 *Ibid* Sch 2 para 6.

31 *Ibid* Sch 2 para 7.

32 *Ibid* s 34(2), (3).

UPDATE

212-229 Veterinary Medicinal Products

Veterinary Medicinal Products Regulations 1997, SI 1997/322 and Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. Provision as to veterinary medicinal products is now made by the Veterinary Medicines Regulations 2009, SI 2009/2297: see PARAS 34A-34D.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(13) HOMOEOPATHIC MEDICINAL PRODUCTS/(ii) Veterinary Medicinal Products/B. REGISTRATION/221. Action on grounds other than grounds relating to safety or quality.

221. Action on grounds other than grounds relating to safety or quality.

If the ministers¹ propose to refuse a registration², to refuse to renew a registration³, to suspend or revoke a registration⁴, or to serve a notice⁵ in relation to the supply of a product⁶ or its withdrawal from the market⁷, on a ground that does not concern the safety or quality of the product⁸, they must not take such action unless, before doing so, they serve a notice⁹ on the applicant, or the person responsible for marketing¹⁰ the product, as the case may be¹¹. The notice must state what action the ministers propose to take¹², their reasons for proposing to take such action¹³, and specify that, on or before the response date specified in the notice, the person¹⁴ on whom such notice is served may make written¹⁵ representations to the ministers with respect to the proposed action¹⁶. Where a person on whom such a notice is served makes written representations to the ministers on or before the response date specified in the notice, the ministers must consider those representations before determining whether to take the proposed action¹⁷.

1 For the meaning of 'the ministers' see PARA 215 note 4 ante.

2 As to registration see PARA 215 ante.

3 As to renewal of registration see PARA 216 ante.

4 As to suspension and revocation of registration see PARA 218 ante.

5 See under the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 10(1): see PARA 219 ante. For the meaning of 'notice' see PARA 219 note 4 ante.

6 For the meaning of 'product' see PARA 212 note 4 ante.

7 As to the meaning of 'market' see PARA 212 note 5 ante.

8 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 12(1). Regulation 12(1) does not apply where the ministers propose to refuse to register a product, or to refuse to renew or to suspend or revoke its registration on the ground specified in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 11 (first paragraph sub-paragraph 3): Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 12(2).

9 As to the service of notices see PARA 37 note 8 ante; provision applied by *ibid* reg 34(1), Sch 5.

10 As to the meaning of 'person responsible for marketing' see PARA 214 note 7 ante.

11 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 12(1), Sch 3 para 1(1).

12 *Ibid* Sch 3 para 1(2)(a).

13 *Ibid* Sch 3 para 1(2)(b).

14 For the meaning of 'person' see PARA 21 note 7 ante.

15 For the meaning of 'written' see PARA 21 note 4 ante; definition applied by the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, Sch 5.

16 *Ibid* Sch 3 para 1(2)(c).

17 Ibid Sch 3 para 2.

UPDATE

212-229 Veterinary Medicinal Products

Veterinary Medicinal Products Regulations 1997, SI 1997/322 and Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. Provision as to veterinary medicinal products is now made by the Veterinary Medicines Regulations 2009, SI 2009/2297: see PARAS 34A-34D.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(13) HOMOEOPATHIC MEDICINAL PRODUCTS/(ii) Veterinary Medicinal Products/C. AUTHORISATIONS/222. Restrictions on the manufacture, import and export of products.

C. AUTHORISATIONS

222. Restrictions on the manufacture, import and export of products.

No person¹ may manufacture² a product³ on or after 1 September 1997 unless it is registered⁴ and he holds an article 24 authorisation⁵ relating to its manufacture, and the manufacture is in accordance with the authorisation⁶; and no person may import⁷ a product from a third country⁸ on or after 1 September 1997 unless it is registered and he holds an article 24 authorisation relating to its import, and the import is in accordance with the authorisation⁹. If a product has been imported into the United Kingdom¹⁰ from a third country and is destined for an EEA state¹¹, no person may export¹² it to an EEA state on or after 1 September 1997 unless it is accompanied by a copy of the article 24 authorisation relating to the import of the product into the United Kingdom¹³.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 As to the meaning of 'manufacture' see PARA 213 note 1 ante.

3 For the meaning of 'product' see PARA 212 note 4 ante.

4 For the meaning of 'registered' see PARA 215 note 5 ante.

5 'Article 24 authorisation' means an authorisation of the type specified in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 24.1: Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 2(1).

6 Ibid reg 22. It is an offence to contravene or fail to comply with this provision: see reg 32(2); and PARA 229 post.

7 'Import' has the same meaning as in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1): Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 22(3), Sch 1 Pt II.

8 'Third countries' has the same meaning as in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1): Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 22(3), Sch 1 Pt II.

9 Ibid reg 23. It is an offence to contravene or fail to comply with this provision: see reg 32(2); and PARA 229 post.

10 For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

11 'EEA state' means a state which is a contracting party to the EEA Agreement other than the United Kingdom: Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 2(1). For the meaning of 'EEA Agreement' see PARA 212 note 2 ante.

12 For the meaning of 'export' see PARA 7 note 4 ante; definition applied by ibid reg 34(1), Sch 5.

13 Ibid reg 24. It is an offence to contravene or fail to comply with this provision: see reg 32(2); and PARA 229 post.

UPDATE

212-229 Veterinary Medicinal Products

Veterinary Medicinal Products Regulations 1997, SI 1997/322 and Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. Provision as to veterinary medicinal products is now made by the Veterinary Medicines Regulations 2009, SI 2009/2297: see PARAS 34A-34D.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(13) HOMOEOPATHIC MEDICINAL PRODUCTS/(ii) Veterinary Medicinal Products/C. AUTHORISATIONS/223. Applications for authorisations.

223. Applications for authorisations.

A person¹ who manufactures² or intends to manufacture a registered³ product⁴, or imports⁵ or intends to import such a product from a third country⁶, may apply to the ministers⁷ for an article 24 authorisation⁸ relating to the manufacture or import, as the case may be⁹. An application must be in writing¹⁰, in the English language, signed by or on behalf of the applicant, and must contain the name and address of the applicant and be accompanied by article 25 particulars¹¹.

Following inquiry¹², the ministers must issue¹³ an applicant with an article 24 authorisation unless they are not satisfied that the accuracy of the article 25 particulars provided by the applicant has been established¹⁴. Where the ministers refuse to issue an article 24 authorisation, they must notify¹⁵ the applicant¹⁶.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 As to the meaning of 'manufacture' see PARA 213 note 1 ante.

3 For the meaning of 'registered' see PARA 215 note 5 ante.

4 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 13(1)(a). For the meaning of 'product' see PARA 212 note 4 ante.

5 As to the meaning of 'import' see PARA 222 note 7 ante.

6 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 13(1)(b). As to the meaning of 'third countries' see PARA 222 note 8 ante.

7 For the meaning of 'the ministers' see PARA 215 note 4 ante.

8 For the meaning of 'article 24 authorisation' see PARA 222 note 5 ante.

9 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 13(1).

10 For the meaning of 'writing' see PARA 21 note 6 ante; definition applied by *ibid* reg 34(1), Sch 5.

11 *Ibid* reg 13(2). 'Article 25 particulars' means particulars which meet the requirements of EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 25(a)-(c), and: (1) where an article 24 authorisation has been issued, it means the article 25 particulars on which such authorisation is based; and (2) where, following the issue of an article 24 authorisation, an article 25 particular is changed in accordance with the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 15 (see PARA 224 post), it means the article 25 particulars as so changed: reg 2(1).

12 *Ie* in accordance with EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 26.1.

13 *Ie* in accordance with the provisions of *ibid* arts 26.2, 26.3, 28.1, 28.3.

14 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 14(1). This provision is expressed to be subject to reg 17 relating to the procedure where the ministers propose to refuse article 24 authorisations: see PARA 225 post.

15 *Ie* in accordance with the provisions of EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 40 (first paragraph).

16 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 14(2).

UPDATE

212-229 Veterinary Medicinal Products

Veterinary Medicinal Products Regulations 1997, SI 1997/322 and Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. Provision as to veterinary medicinal products is now made by the Veterinary Medicines Regulations 2009, SI 2009/2297: see PARAS 34A-34D.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(13) HOMOEOPATHIC MEDICINAL PRODUCTS/(ii) Veterinary Medicinal Products/C. AUTHORISATIONS/224. Change of particulars; suspension and revocation of authorisations.

224. Change of particulars; suspension and revocation of authorisations.

A request to change an article 25 particular¹ on which an article 24 authorisation² is based may be made to the ministers³ by the holder⁴ of the authorisation⁵. Where such a request is made, the ministers must authorise⁶ the change in the article 25 particulars unless they are not satisfied that the authorisation holder will continue to meet the relevant requirements⁷ if the change in the particulars is made⁸. Where the ministers authorise a change in the article 25 particulars, they must make any necessary amendments to the article 24 authorisation in question⁹.

The ministers must suspend or revoke an article 24 authorisation if they are not satisfied that the authorisation holder is complying with the article 25 particulars on which the authorisation is based¹⁰; and, if they are not satisfied that the holder of an article 24 authorisation has complied with the duties imposed¹¹ on him, the ministers may suspend or revoke such an authorisation in relation to all registered¹² products¹³ to which the authorisation relates¹⁴, or in relation to one or some of such products¹⁵. Where the ministers suspend or revoke an article 24 authorisation, they must notify¹⁶ the authorisation holder¹⁷.

1 For the meaning of 'article 25 particulars' see PARA 223 note 11 ante.

2 For the meaning of 'article 24 authorisation' see PARA 222 note 5 ante.

3 For the meaning of 'the ministers' see PARA 215 note 4 ante.

4 As to references to the holder of an authorisation see PARA 66 note 5 ante; definition applied by the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 34(1), Sch 5.

5 Ibid reg 15(1).

6 Ie in accordance with the provisions of EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 28.2, 28.3.

7 Ie of ibid art 25.

8 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 15(2).

9 Ibid reg 15(3).

10 Ibid reg 16(1). This provision is expressed to be subject to reg 17 relating to the procedure where the ministers propose to suspend or revoke article 24 authorisations: see PARA 225 post.

11 Ie by ibid reg 25: see PARA 227 post.

12 For the meaning of 'registered' see PARA 215 note 5 ante.

13 For the meaning of 'product' see PARA 212 note 4 ante.

14 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 16(2)(a).

15 Ibid reg 16(2)(b).

16 Ie in accordance with the provisions of EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 40 (first paragraph).

17 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 16(3).

UPDATE

212-229 Veterinary Medicinal Products

Veterinary Medicinal Products Regulations 1997, SI 1997/322 and Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. Provision as to veterinary medicinal products is now made by the Veterinary Medicines Regulations 2009, SI 2009/2297: see PARAS 34A-34D.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(13) HOMOEOPATHIC MEDICINAL PRODUCTS/(ii) Veterinary Medicinal Products/C. AUTHORISATIONS/225. Procedure on proposals to refuse, or to suspend or revoke, authorisations.

225. Procedure on proposals to refuse, or to suspend or revoke, authorisations.

If the ministers¹ propose to refuse to issue² or to suspend or revoke³ an article 24 authorisation⁴, the ministers must not take such action unless, before doing so, they serve a notice⁵ on the applicant or the authorisation holder⁶, as the case may be⁷. Such a notice must state what action⁸ the ministers propose to take⁹, state their reasons for proposing to take such action¹⁰, and specify that, on or before the response date specified in the notice, the person¹¹ on whom such notice is served may make written¹² representations to the ministers with respect to the proposed action¹³.

Where a person on whom such notice is served makes written representations to the ministers on or before the response date specified in the notice, the ministers must consider those representations before determining whether to take the proposed action¹⁴.

1 For the meaning of 'the ministers' see PARA 215 note 4 ante.

2 As to applications for authorisations see PARA 223 ante.

3 As to the suspension or revocation of authorisations see PARA 224 ante.

4 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 17. For the meaning of 'article 24 authorisation' see PARA 222 note 5 ante.

5 For the meaning of 'notice' see PARA 219 note 4 ante. As to the service of notices see PARA 37 note 8 ante; provision applied by *ibid* reg 34(1), Sch 5.

6 As to references to the holder of an authorisation see PARA 66 note 5 ante; definition applied by *ibid* reg 34(1), Sch 5.

7 *Ibid* reg 17, Sch 4 para 1(1).

8 *Ie* under *ibid* reg 17: see the text to notes 1-4 *supra*.

9 *Ibid* Sch 4 para 1(2)(a).

10 *Ibid* Sch 4 para 1(2)(b).

11 For the meaning of 'person' see PARA 21 note 7 ante.

12 For the meaning of 'written' see PARA 21 note 4 ante; definition applied by the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, Sch 5.

13 *Ibid* Sch 4 para 1(2)(c).

14 *Ibid* Sch 4 para 2.

UPDATE

212-229 Veterinary Medicinal Products

Veterinary Medicinal Products Regulations 1997, SI 1997/322 and Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products.

Provision as to veterinary medicinal products is now made by the Veterinary Medicines Regulations 2009, SI 2009/2297: see PARAS 34A-34D.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(13) HOMOEOPATHIC MEDICINAL PRODUCTS/(ii) Veterinary Medicinal Products/C. AUTHORISATIONS/226. Issue of certificates.

226. Issue of certificates.

Where requested to do so by a manufacturer¹ of a registered² product³ who holds an article 24 authorisation⁴, the exporter⁵ of a product manufactured by such a manufacturer⁶, or the authorities of a third country⁷ into which such a product is to be imported⁸, the ministers⁹ must certify that the manufacturer is in possession of an article 24 authorisation¹⁰.

1 As to the meaning of 'manufacture' see PARA 213 note 1 ante.

2 For the meaning of 'registered' see PARA 215 note 5 ante.

3 For the meaning of 'product' see PARA 212 note 4 ante.

4 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 29(a). For the meaning of 'article 24 authorisation' see PARA 222 note 5 ante.

5 For the meaning of 'export' see PARA 7 note 4 ante; definition applied by *ibid* reg 34(1), Sch 5.

6 *Ibid* reg 29(b).

7 As to the meaning of 'third countries' see PARA 222 note 8 ante.

8 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 29(c). As to the meaning of 'import' see PARA 222 note 7 ante.

9 For the meaning of 'the ministers' see PARA 215 note 4 ante.

10 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 29.

UPDATE

212-229 Veterinary Medicinal Products

Veterinary Medicinal Products Regulations 1997, SI 1997/322 and Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. Provision as to veterinary medicinal products is now made by the Veterinary Medicines Regulations 2009, SI 2009/2297: see PARAS 34A-34D.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(13) HOMOEOPATHIC MEDICINAL PRODUCTS/(ii) Veterinary Medicinal Products/C. AUTHORISATIONS/227. Duties on holders of authorisations.

227. Duties on holders of authorisations.

The holder¹ of an article 24 authorisation² must³: (1) comply with the applicable provisions⁴; (2) comply with the applicable principles and guidelines⁵ of good manufacturing practice⁶; (3) keep⁷ a detailed record⁸ in respect of a registered⁹ product¹⁰ or sample¹¹ of such product supplied by him¹²; (4) make such record available to the relevant enforcement authority¹³ for inspection for a period of three years from and including the date on which such record is made¹⁴; (5) have permanently and continuously at his disposal¹⁵ the services of at least one qualified person¹⁶ who is responsible in particular for carrying out the specified¹⁷ duties¹⁸; and (6) furnish the relevant enforcement authority, upon request, with proof that he has carried out the applicable¹⁹ control tests²⁰.

1 As to references to the holder of an authorisation see PARA 66 note 5 ante; definition applied by the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 34(1), Sch 5.

2 For the meaning of 'article 24 authorisation' see PARA 222 note 5 ante.

3 It is an offence to contravene or fail to comply with any provision of the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 25: see reg 32(2); and PARA 229 post.

4 Ibid reg 25(a). The applicable provisions are those of EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 27(a)-(e). See also note 3 supra.

5 Ie set out in EC Commission Directive 91/412 (OJ L228, 17.8.1991, p 70) laying down the principles and guidelines of good manufacturing practice for veterinary medicinal products, arts 4-14, as interpreted in accordance with art 3 (second paragraph): Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, regs 2(1), 25(b).

6 Ibid reg 25(b). See also note 3 supra.

7 Ie in accordance with the provisions of EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 27(g).

8 'Detailed record' has the same meaning as in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1): Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 2(3), Sch 1 Pt II.

9 For the meaning of 'registered' see PARA 215 note 5 ante.

10 For the meaning of 'product' see PARA 212 note 4 ante.

11 'Sample' has the same meaning as in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1): Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 2(3), Sch 1 Pt II.

12 Ibid reg 25(c). See also note 3 supra.

13 For the meaning of 'the relevant enforcement authority' see PARA 229 note 1 post.

14 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 25(d). See also note 3 supra.

15 'Permanently and continuously at his disposal' has the same meaning as in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1): Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 2(3), Sch 1 Pt II.

16 The holder of the authorisation may himself be the qualified person if he fulfils the conditions laid down in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 31: Registration of Homoeopathic Veterinary Medicinal

Products Regulations 1997, SI 1997/322, reg 25(e). For the meaning of 'qualified person' see PARA 228 note 1 post.

17 le specified in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 30.

18 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 25(e). See also note 3 supra.

19 le specified in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 35.

20 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 25(f). See also note 3 supra.

UPDATE

212-229 Veterinary Medicinal Products

Veterinary Medicinal Products Regulations 1997, SI 1997/322 and Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. Provision as to veterinary medicinal products is now made by the Veterinary Medicines Regulations 2009, SI 2009/2297: see PARAS 34A-34D.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(13) HOMOEOPATHIC MEDICINAL PRODUCTS/(ii) Veterinary Medicinal Products/C. AUTHORISATIONS/228. Qualified persons.

228. Qualified persons.

A qualified person¹ must carry out the specified² duties³. Where the qualified person certifies⁴ a batch⁵ of a registered⁶ product⁷ in a register or equivalent document⁸, he must keep the register or equivalent document at the disposal of the relevant enforcement authority⁹ for a period of five years from and including the date on which the certification is made¹⁰.

Where it appears to the ministers¹¹ that a person acting as a qualified person does not satisfy the specified¹² requirements¹³, or has failed to comply with his obligations¹⁴, the ministers must serve a notice¹⁵ on that person¹⁶. Such a notice must notify the person on whom it is served that the ministers propose to serve a suspension notice on him directing him not to act as a qualified person¹⁷; state the reasons why the ministers are proposing to serve such a notice¹⁸; and specify that, on or before the response date specified in the notice, the notified person may make written¹⁹ representations to the ministers in connection with such proposed notice or reasons²⁰.

Where the ministers decide not to serve a suspension notice on a notified person, they must notify him of their decision²¹. Where the ministers decide to serve a suspension notice on a notified person, they must serve a notice on him directing him not to act as a qualified person²². During the period in which a suspension notice is in force in relation to a notified person that person must not act as a qualified person²³, and no other person must permit that person to act for him as a qualified person²⁴.

1 'Qualified person' means a person, other than a person in respect of whom a suspension notice served under the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 27(4) (see the text to note 22 infra) is in force, who fulfils the conditions laid down in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 31, or is eligible to act as a qualified person by virtue of art 32: Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 2(1).

2 Ie specified in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 30.

3 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 26(1). It is an offence to contravene or fail to comply with this provision: see reg 32(2); and PARA 229 post.

4 Ie in accordance with EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 30.2.

5 As to the meaning 'batch' see PARA 219 note 8 ante.

6 For the meaning of 'registered' see PARA 215 note 5 ante.

7 For the meaning of 'product' see PARA 212 note 4 ante.

8 'Register or equivalent document' has the same meaning as in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1): Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 2(3), Sch 1 Pt II.

9 For the meaning of 'the relevant enforcement authority' see PARA 229 note 1 post.

10 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 26(2). It is an offence to contravene or fail to comply with this provision: see reg 32(2); and PARA 229 post.

11 For the meaning of 'the ministers' see PARA 215 note 4 ante.

12 Ie specified in EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 31 or art 32.

- 13 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 27(1)(a).
- 14 Ibid reg 27(1)(b). The obligations referred to are those in reg 26: see the text to notes 1-10 *supra*.
- 15 For the meaning of 'notice' see PARA 219 note 4 *ante*. As to the service of notices see PARA 37 note 8 *ante*; provision applied by *ibid* reg 34(1), Sch 5.
- 16 Ibid reg 27(1). Such a person is called 'the notified person': reg 27(1).
- 17 Ibid reg 27(2)(a).
- 18 Ibid reg 27(2)(b).
- 19 For the meaning of 'written' see PARA 21 note 4 *ante*; definition applied by *ibid* reg 34(1), Sch 5.
- 20 Ibid reg 27(2)(c).
- 21 Ibid reg 27(3).
- 22 Ibid reg 27(4). A suspension notice served on a notified person under reg 27(4) may be revoked at any time by the ministers serving a notice on the notified person notifying him that he may resume acting as a qualified person: reg 27(5).
- 23 Ibid reg 27(6)(a). It is an offence to contravene or fail to comply with this provision: see reg 32(2); and PARA 229 *post*.
- 24 Ibid reg 27(6)(b). It is an offence to contravene or fail to comply with this provision: see reg 32(2); and PARA 229 *post*.

UPDATE

212-229 Veterinary Medicinal Products

Veterinary Medicinal Products Regulations 1997, SI 1997/322 and Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. Provision as to veterinary medicinal products is now made by the Veterinary Medicines Regulations 2009, SI 2009/2297: see PARAS 34A-34D.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(13) HOMOEOPATHIC MEDICINAL PRODUCTS/(ii) Veterinary Medicinal Products/D. ENFORCEMENT AND OFFENCES/229. Enforcement; offences.

D. ENFORCEMENT AND OFFENCES

229. Enforcement; offences.

It is the duty of the relevant enforcement authority¹ to enforce the provisions of the regulations² relating to the registration of homoeopathic veterinary medicinal products³.

Any person⁴ who contravenes or fails to comply with any provision relating to the restrictions on the marketing of products⁵, the prohibitions on the supply of a product or its withdrawal from the market⁶, or as to confidentiality⁷, is guilty of an offence⁸. Any person who contravenes or fails to comply with any provision relating to the duties on persons responsible for marketing⁹ registered¹⁰ products¹¹, labelling and package inserts¹², the restrictions on the manufacture¹³ of products¹⁴, the restrictions on imports¹⁵, the restrictions on exports¹⁶, the duties on holders of article 24 authorisations¹⁷, the duties on qualified persons¹⁸, or suspension notices in respect of qualified persons¹⁹, is guilty of an offence²⁰.

Where a person responsible for marketing a registered product is charged with an offence in respect of anything which has been manufactured or assembled²¹ to his order by another person and which has been so manufactured or assembled as not to comply with his order, it is a defence for him to prove: (1) that, in placing his order, a copy of the documents forming part of the article 8 dossier²² relating to the manufacture and assembly of the product were available, or had been provided, to that other person and the person responsible for marketing the registered product had instructed that other person to manufacture or assemble the product in accordance with those documents or dossier²³; and (2) that the person responsible for marketing the registered product did not know, and could not by the exercise of reasonable care have known, that those instructions had not been complied with²⁴.

1 'The relevant enforcement authority' means the Secretary of State: Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 2(1); Ministry of Agriculture, Fisheries and Food (Dissolution) Order 2002, SI 2002/794. As to the Secretary of State see PARA 3 note 3 ante.

2 *Ie* of the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322.

3 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 31. For the meaning of 'homoeopathic veterinary medicinal product' see PARA 212 note 2 ante. Such duty is deemed to be a duty imposed by the Medicines Act 1968 s 108(1) (see PARA 168 ante): Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 31. It is the duty of the relevant enforcement authority to comply with EC Council Directive 81/851 (OJ L317, 6.11.1981, p 1) art 34: reg 30.

4 For the meaning of 'person' see PARA 21 note 7 ante.

5 *Ie* the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 18: see PARA 214 ante. As to the meaning of 'market' see PARA 212 note 5 ante. For the meaning of 'product' see PARA 212 note 4 ante.

6 *Ie* *ibid* reg 20: see PARA 219 ante.

7 *Ie* *ibid* reg 28: see PARA 213 ante.

8 *Ibid* reg 32(1). Such a person is liable on summary conviction to a fine not exceeding level 5 on the standard scale: see reg 32(1). As to the standard scale see PARA 6 note 22 ante. As to a defence to this offence see the text and notes 21-24 *infra*.

- 9 As to the meaning of 'person responsible for marketing' see PARA 214 note 7 ante.
- 10 For the meaning of 'registered' see PARA 215 note 5 ante.
- 11 le the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 19: see PARA 214 ante.
- 12 le ibid reg 21: see PARA 214 ante. For the meanings of 'labelling' and 'package' see PARA 152 note 4 ante; definitions applied by reg 34(1), Sch 5.
- 13 As to the meaning of 'manufacture' see PARA 213 note 1 ante.
- 14 le the Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 22: see PARA 222 ante.
- 15 le ibid reg 23: see PARA 222 ante. As to the meaning of 'import' see PARA 222 note 7 ante.
- 16 le ibid reg 24: see PARA 222 ante. For the meaning of 'export' see PARA 7 note 4 ante; definition applied by reg 34(1), Sch 5.
- 17 le ibid reg 25: see PARA 227 ante. For the meaning of 'article 24 authorisation' see PARA 222 note 5 ante.
- 18 le ibid reg 26: see PARA 228 ante. For the meaning of 'qualified person' see PARA 228 note 1 ante.
- 19 le ibid reg 27(6): see PARA 228 ante.
- 20 Ibid reg 32(2). Such a person is liable on summary conviction to a fine not exceeding level 3 on the standard scale: see reg 32(2). As to a defence to this offence see the text and notes 21-24 infra.
- 21 For the meaning of 'assemble' see PARA 6 note 8 ante; definition applied by ibid reg 34(1), Sch 5.
- 22 For the meaning of 'article 8 dossier' see PARA 217 note 1 ante.
- 23 Registration of Homoeopathic Veterinary Medicinal Products Regulations 1997, SI 1997/322, reg 33(1).

UPDATE

UPDATE

212-229 Veterinary Medicinal Products

Veterinary Medicinal Products Regulations 1997, SI 1997/322 and Medicines (Products for Animal Use--Fees) Regulations 2004, SI 2004/2750 revoked: SI 2005/2745. The Medicines Act 1968 no longer applies in relation to veterinary medicinal products. Provision as to veterinary medicinal products is now made by the Veterinary Medicines Regulations 2009, SI 2009/2297: see PARAS 34A-34D.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/1. CONTROL OF MEDICINAL PRODUCTS/(14) TRADITIONAL HERBAL MEDICINAL PRODUCTS/230. Regulation of traditional herbal medicinal products.

(14)

230. Regulation of traditional herbal medicinal products.

Except in accordance with specified exceptions or exemptions¹, no traditional herbal medicinal product² may be placed on the market and no such product may be distributed by way of wholesale dealing³, unless a traditional herbal registration⁴ in respect of that product has been granted by the licensing authority and is for the time being in force⁵.

Every application for the grant or renewal of a traditional herbal registration must be made in accordance with the specified requirements⁶; and the applicant for the grant or renewal of a traditional herbal registration must be established in the Community⁷. The licensing authority must consider every application for the grant, renewal or variation of a traditional herbal registration in accordance with the relevant Community provisions⁸ and, where applicable, the rules of Community law relating to parallel imports⁹; and it must grant, renew or vary, or refuse to grant, renew or vary, the registration in accordance with those provisions¹⁰. Each traditional herbal registration granted by the licensing authority must be granted subject to a condition that the traditional herbal medicinal product to which the registration relates is to be available only from a pharmacy¹¹ or on general sale¹²; and specific provisions relating to labels apply in certain circumstances¹³.

The licensing authority has powers to revoke, suspend or vary a traditional herbal registration and to require the holder of a traditional herbal registration to suspend the use, supply or marketing within the United Kingdom of a traditional herbal medicinal product¹⁴. The authority may also impose an urgent safety restriction on the holder of a traditional herbal registration¹⁵, in response to which the holder of the traditional herbal registration must implement the restriction within a period specified by the licensing authority and apply to vary the registration so as to take account of that safety restriction within the time limits stipulated¹⁶.

Every holder of a traditional herbal registration must comply with all obligations which relate to him by virtue of the relevant Community provisions including, in particular, obligations relating to providing or updating information, making changes, applying to vary the traditional herbal registration, pharmacovigilance, and labels and package leaflets¹⁷. Certain records and documents must be kept by the holder of a registration¹⁸ and certain information must be given by him to the licensing authority¹⁹.

There are a number of criminal offences in connection with the obligations of applicants for, and holders of, traditional herbal registrations and certain other persons²⁰.

The enforcement provisions of the Medicines Act 1968²¹ apply for the purposes of the regulation of traditional herbal medicinal products²².

¹ ie the exceptions or exemptions set out in: (1) the provisions of EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) on the Community code relating to medicinal products for human use (as amended) which apply to traditional herbal medicinal products and to traditional herbal registrations; and (2) the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, SI 2005/2750, reg 4, Sch 1.

² Expressions used in the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, SI 2005/2750, which are also used in EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) (as amended) have the same meanings as they have in the Directive; and related expressions are to be

construed accordingly: Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, SI 2005/2750, reg 2(2).

3 As to the meaning of 'wholesale dealing' see PARA 47 note 5 ante; definition applied by *ibid* reg 2(3).

4 'Traditional herbal registration' means a registration granted by the licensing authority under the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, SI 2005/2750, and includes a parallel import licence: reg 2(1). 'Parallel import licence' means a traditional herbal registration granted by the licensing authority under the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, SI 2005/2750, in respect of a traditional herbal medicinal product which is imported into the United Kingdom from another EEA state in accordance with the rules of Community law relating to parallel imports: reg 2(1). For the meaning of 'the licensing authority' see PARA 43 note 8 ante; definition applied by reg 2(1). For the meaning of 'United Kingdom' see PARA 7 note 3 ante. 'EEA state' means a member state, Norway, Iceland or Liechtenstein: reg 2(1). For the meaning of 'member state' see the European Communities Act 1972 s 1(2), Sch 1 Pt II; and the Interpretation Act 1978 s 5, Sch 1. As to the validity of traditional herbal registrations and PARALLEL import licences see the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, SI 2005/2750, reg 6(3)-(6).

5 See *ibid* reg 4(1). The provisions of the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, SI 2005/2750, do not apply until 30 April 2011 to herbal medicinal products which were on the market in the United Kingdom on 30 April 2004 without a marketing authorisation by virtue of the Medicines Act 1968 s 12(2) (see PARA 53 ante): Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, SI 2005/2750, reg 12, Sch 6.

The provisions of the Trade Descriptions Act 1968 apply to the application of a trade description to goods subject to a traditional herbal registration in the same way as, by virtue of s 2(5)(b) (see SALE OF GOODS AND SUPPLY OF SERVICES vol 41 (2005 Reissue) PARA 482), they apply to the application of a trade description to goods subject to any provision made under the Medicines Act 1968 Pt V (ss 85-91) (see PARA 152 et seq ante): Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, SI 2005/2750, reg 10(5).

The Consumer Protection Act 1987 s 19(1) has effect as if in the definition of 'licensed medicinal product' (see SALE OF GOODS AND SUPPLY OF SERVICES vol 41 (2005 Reissue) PARA 534) the reference to any medicinal product within the meaning of the Medicines Act 1968 in respect of which a product licence within the meaning of that Act is for the time being in force included a reference to a traditional herbal medicinal product in respect of which a traditional herbal registration is for the time being in force: Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, SI 2005/2750, reg 10(7). As to consumer safety generally see SALE OF GOODS AND SUPPLY OF SERVICES vol 41 (2005 Reissue) PARA 528 et seq.

The Medicines Act 1968 s 7 (general provisions as to dealing with medicinal products: see PARA 44 ante), and s 56 (exemptions in respect of herbal remedies: see PARA 138 ante) do not apply in relation to traditional herbal medicinal products: Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, SI 2005/2750, reg 10(1), (3). The Medicines Act 1968 s 23 (special provisions as to effect of manufacturer's licence: see PARA 66 ante) and s 61 (special restrictions on persons to be supplied with medicinal products: see PARA 144 ante) have effect in relation to a traditional herbal registration: see the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, SI 2005/2750, reg 10(2), (4).

6 See *ibid* reg 5. As to the requirements see reg 5(1)-(4), (6). The Medicines Act 1971 s 1(1) (fees payable for purposes of the Medicines Act 1968 Pt II (ss 6-50) (as amended): see PARA 11 ante) has effect as if the reference to any application in pursuance of the Medicines Act 1968 for a licence under Pt II (as amended) or for the variation or renewal of such a licence included a reference to any application for a traditional herbal registration or for the variation or renewal of such a registration: Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, SI 2005/2750, reg 10(6).

7 *Ibid* reg 5(5).

8 The relevant Community provisions are those set out in head (1) of note 1 *supra*.

9 Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, SI 2005/2750, reg 6(1) (a).

10 *Ibid* reg 6(1)(b). As to the procedure for receiving advice and representations before granting, renewing or varying, or refusing to grant, renew, or vary, a traditional herbal registration, or after notification of a decision relating to an application to vary such a registration, see Sch 2.

11 *Ibid* reg 6(7)(a).

12 *Ibid* reg 6(7)(b).

13 See *ibid* reg 12, Sch 5.

14 See *ibid* reg 7. As to the procedure for receiving advice and representations before the revocation, variation or suspension of a traditional herbal registration see Sch 2.

15 See *ibid* reg 8(1).

16 See *ibid* reg 8(2).

17 *Ibid* reg 9(1).

18 See *ibid* reg 9(2), (3).

19 See *ibid* reg 9(4), (5), (7).

20 See *ibid* reg 9(6), Sch 3.

21 See the Medicines Act 1968 ss 107-108 (see PARAS 79, 168 ante), ss 111-116 (see PARAS 169-173 ante), ss 118-119 (see PARAS 174-175 ante), ss 121-126 (see PARAS 179-181, 183-184 ante), s 127 (see PARA 37 note 8 ante) and Sch 3 (see PARA 171 ante).

22 See the Medicines (Traditional Herbal Medicinal Products for Human Use) Regulations 2005, SI 2005/2750, reg 11(1). The provisions apply with modifications: see reg 11(2) Sch 4.

UPDATE

230 Regulation of traditional herbal medicinal products

NOTE 1--SI 2005/2750 Sch 1 amended: SI 2006/914.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/2. MEDICAL DEVICES/231. Meaning of 'medical device'.

2. MEDICAL DEVICES

231. Meaning of 'medical device'.

'Medical device' means an instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any software necessary for its proper application, which:

- 205 (1) is intended by the manufacturer¹ to be used for human beings for the purpose of:
- 25
- 29. (a) diagnosis, prevention, monitoring, treatment or alleviation of disease;
 - 30. (b) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
 - 31. (c) investigation, replacement or modification of the anatomy or of a physiological process; or
 - 32. (d) control of conception; and
- 26
- 206 (2) does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, even if it is assisted in its function by such means,

and includes devices intended to administer a medicinal product² or which incorporate as an integral part a substance which, if used separately, would be a medicinal product and which is liable to act upon the body with action ancillary to that of the device³.

However, the regulations⁴ regulating medical devices do not apply to: (i) medicinal products⁵ for human use⁶; (ii) human blood, human blood products, plasma or blood cells of human origin⁷; (iii) devices that incorporate, at the time of placing on the market, human blood, blood products, plasma or blood cells of human origin, except for stable derivatives devices⁸; (iv) transplants or tissues⁹ or cells of human origin or products incorporating or derived from tissues or cells of human origin¹⁰; (v) transplants or tissues or cells of animal¹¹ origin, unless a device is manufactured utilising animal tissue which is rendered non-viable¹² or non-viable products derived from animal tissue¹³; (vi) cosmetic products¹⁴; or (vii) products whose principal intended purpose is such that they fall under legislation¹⁵ relating to personal protective equipment¹⁶.

1 'Manufacturer' means: (1) the person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party; or (2) any other person who assembles, packages, processes, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name, apart from a person who assembles or adapts devices already on the market to their intended purpose for an individual patient: Medical Devices Regulations 2002, SI 2002/618, reg 2(1). For the meaning of 'person' see PARA 21 note 7 ante. 'Placing on the market' means, in relation to a medical device, the first making available in return for payment or free of charge of a new or fully refurbished device, other than a device intended for clinical investigation, with a view to distribution, use, or both, on the Community market: reg 2(1). 'Intended purpose' means, in relation to an active implantable medical device, the use for which it is intended and for which it is suited according to the data supplied by the manufacturer in the instructions relating to it; and, in relation to any other medical device, the use to which the device is intended according to the data supplied by the manufacturer on the labelling, the instructions for use and/or the promotional materials: reg 2(1). For the meaning of 'active implantable medical device' see PARA 233 note 4 post. 'Intended for clinical investigation'

means, in relation to an active implantable medical device, that it is intended for use by a medical specialist when conducting clinical investigations of that device; and, in relation to any other medical device, that it is intended for use by a duly qualified medical practitioner or a professional user when conducting investigations of that device in an adequate human clinical environment: reg 2(1). 'Medical specialist' means a registered medical practitioner (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 4) who has a qualification as, or is undergoing training intended to lead to qualification as, a specialist: reg 2(1). For these purposes, 'the Community' means, in the context of any requirement relating to an in vitro diagnostic medical device, the European Community and, in the context of any requirement relating to any other medical device, the European Economic Area; and 'European Economic Area' means the European Economic Area created by the Agreement on the European Economic Area (Oporto, 2 May 1992; EC 7 (1992); Cm 2183) as adjusted by the Protocol (Brussels, 17 March 1993; EC 2 (1993); Cm 2183) ('the EEA Agreement'): Medical Devices Regulations 2002, SI 2002/618, reg 2(1). For the meaning of 'in vitro diagnostic medical device' see PARA 234 note 4 post.

2 'Medicinal product' has the meaning given in EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) on the Community code relating to medicinal products for human use, art 1.2: see the Medical Devices Regulations 2002, SI 2002/618, reg 2(1).

3 Ibid reg 2(1). In certain circumstances a fee is payable in connection with consultations with the competent body in relation to the safety, quality and usefulness of a medicinal substance incorporated in a medical device: see the Medical Devices (Consultation Requirements) (Fees) Regulations 1995, SI 1995/449 (amended by SI 2005/2759).

4 Ie the Medical Devices Regulations 2002, SI 2002/618 (as amended).

5 Ie governed by EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67), including medicinal products derived from human blood or human plasma governed by EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) Title X.

6 Medical Devices Regulations 2002, SI 2002/618, reg 3(a).

7 Ibid reg 3(b).

8 Ibid reg 3(c). 'Stable derivatives device' means a medical device that contains human blood, blood products, plasma or blood cells of human origin, and which incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product constituent or a medicinal product derived from human blood or human plasma within the meaning of EC Parliament and Council Directive 2001/83 (OJ L311, 28.11.2001, p 67) art 1.10 and which is liable to act upon the human body with action ancillary to that of the device: Medical Devices Regulations 2002, SI 2002/618, reg 2(1).

9 'Tissue' means an organisation of cells and/or extra-cellular constituents: ibid reg 2(1) (definition added by SI 2003/1697).

10 Medical Devices Regulations 2002, SI 2002/618, reg 3(d).

11 For these purposes, 'animal' means any animal from a bovine, ovine or caprine species, as well as deer, elk, mink and cats: ibid reg 2(1).

12 'Non-viable' means having no potential for metabolism or multiplication: ibid reg 2(1).

13 Ibid reg 3(e).

14 Ibid reg 3(f). The cosmetic products referred to in the text are those governed by EC Council Directive 76/768 (OJ L262, 27.9.1976, p 169) (as amended): Medical Devices Regulations 2002, SI 2002/618, reg 3(f). See *Optident Ltd v Secretary of State for Trade and Industry* [2001] UKHL 32, [2001] CMLR 1, 61 BMLR 10, (whether product should be classified as a cosmetic or a medical device).

15 Ie EC Council Directive 89/686 (OJ L399, 30.12.1989, p 18) on the approximation of the laws of the member states (as amended): Medical Devices Regulations 2002, SI 2002/618, reg 3(g).

16 Ibid reg 3(g).

UPDATE

231 Meaning of 'medical device'

NOTE 1--'Intended for clinical investigation' now means intended for use by a registered medical practitioner when conducting investigations of that device in an adequate human clinical environment; or intended for use by any other person in a member state who, by virtue of their professional qualification, is authorised to carry out investigations of that device in an adequate human clinical environment: SI 2002/618 reg 2(1) (definition substituted by SI 2008/2936 with effect from 21 March 2010). Definition of 'medical specialist' revoked in consequence: SI 2008/2936.

NOTE 3--SI 1995/449 further amended: SI 2006/494, SI 2007/803, SI 2008/503, SI 2009/383.

TEXT AND NOTE 10--SI 2002/618 reg 3(d) amended: SI 2007/400, SI 2008/2936 (with effect from 21 March 2010).

TEXT AND NOTE 13--SI 2002/618 reg 3(e) substituted by SI 2007/400 and amended (with effect from 21 March 2010) by SI 2008/2936.

TEXT AND NOTES 15, 16--SI 2002/618 reg 3(g) revoked: SI 2008/2936 (with effect from 21 March 2010).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/2. MEDICAL DEVICES/232. General medical devices.

232. General medical devices.

No person¹ may place on the market² or put into service³ a relevant device⁴ unless that device meets those essential requirements⁵ which apply to it⁶; and no person may supply⁷ a relevant device if that supply is also a placing on the market or putting into service of that device⁸, or in circumstances where that device has been placed on the market or put into service⁹, unless that device meets those essential requirements¹⁰ which apply to it¹¹.

Restrictions are imposed on the placing on the market, putting into service, and supply of general medical devices unless the device, packaging or instructions for use bear a CE marking¹²; and there are restrictions on the affixing of a CE marking to general medical devices¹³. Restrictions are also placed on the supply of custom-made devices¹⁴, and on the supply of general medical devices for the purposes of a clinical investigation in the United Kingdom¹⁵. Manufacturers of general medical devices must follow certain procedures¹⁶, and provision is made for conformity assessments of such devices¹⁷. Persons placing general medical devices on the market must provide the Secretary of State with prescribed information¹⁸.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 For the meaning of 'placing on the market' see PARA 231 note 1 ante.

3 'Putting into service' means: (1) in relation to an active implantable medical device, the making available of the device to a registered medical practitioner for implantation; (2) in relation to any other medical device, the first making available of the device in the Community to a final user, including where a device is used in a professional context for the purposes of medical analysis without being marketed: Medical Devices Regulations 2002, SI 2002/618, reg 2(1). For the meaning of 'active implantable medical device' see PARA 233 note 4 post. For the meaning of 'medical device' see PARA 231 ante. For the meaning of 'registered medical practitioner' see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 4. For the meaning of 'the Community' see PARA 231 note 1 ante.

4 'Relevant device' means medical devices (including stable derivatives devices), accessories to such devices, single-use combination products, and systems and procedure packs, other than:

77 (1) active implantable medical devices and accessories to such devices (ibid regs 5(1), 6(a));

78 (2) in vitro diagnostic medical devices and accessories to such devices (regs 5(1), 6(b)); and

79 (3) devices that come within the scope of EC Council Directive 93/42 (OJ L169, 12.7.1993, p 1) of 14 June 1993 concerning medical devices (as amended) and another Directive ('the other Directive') issued by one or more of the institutions of the Community, if: (a) the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it; and (b) the manufacturer chooses to follow the set of arrangements in the other Directive (Medical Devices Regulations 2002, SI 2002/618, regs 2(1), 5(1), 6(c)(i), (ii)).

For the meaning of 'stable derivatives device' see PARA 231 note 8 ante; and for the meaning of 'manufacturer' see PARA 231 note 1 ante. For the meaning of 'in vitro diagnostic medical device' see PARA 234 note 4 post. 'Accessory' means an article which, whilst not being a medical device, is intended specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of the medical device intended by its manufacturer; 'single-use combination product' means a product which comprises a medical device and medicinal product forming a single integral product which is intended exclusively for use in the given combination and which is not reusable; and 'system or procedure pack' has the same meaning as in EC Council Directive 93/42 (OJ L169, 12.7.1993, p 1) art 12: Medical Devices Regulations 2002, SI 2002/618, reg 5(1). For the meaning of 'medicinal product' see PARA 231 note 2 ante.

The Medical Devices Regulations 2002, SI 2002/618, Pt II (regs 5-19A) (as amended) must not be applied: (i) before 10 January 2007 in respect of a stable derivatives device placed on the market without a CE marking, if

the device satisfies the requirements of the laws of that part of the United Kingdom in which it is placed on the market as in force on 10 January 2002 (reg 4(2)(a)); or (ii) before 10 January 2009 in respect of a stable derivatives device put into service without a CE marking, if the device satisfies the requirements of the laws of that part of the United Kingdom in which it is placed on the market as in force on 10 January 2002 (reg 4(2)(b)). 'CE marking' means a conformity marking consisting of the initials 'CE': reg 2(1). For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

5 Ie set out in EC Council Directive 93/42 (OJ L169, 12.7.1993, p 1) Annex I: Medical Devices Regulations 2002, SI 2002/618, regs 5(2), 8(1). As to the determination of the compliance of general medical devices with essential requirements see reg 9.

6 Ibid reg 8(1). There are additional requirements relating to the use of animal tissues: see reg 19A (added by SI 2003/1697). For the meaning of 'animal' see PARA 231 note 11 ante; and for the meaning of 'tissue' see PARA 231 note 9 ante. As to the classification of general medical devices see the Medical Devices Regulations 2002, SI 2002/618, reg 7 (amended by SI 2003/1697). A relevant device or a single use combination product being shown at a trade fair, exhibition, demonstration or similar gathering is not being placed on the market or put into service if a visible sign clearly indicates that the device or product cannot be marketed or put into service until it complies with the requirements of EC Council Directive 93/42 (OJ L169, 12.7.1993, p 1) or the Medical Devices Regulations 2002, SI 2002/618 (as amended): reg 12(1). Regulation 8 does not apply where, following a duly justified request and in the interests of the protection of health, the Secretary of State has authorised, where appropriate for a specified period, the placing on the market or putting into service of a particular relevant device or relevant devices of a particular class or description without a CE marking, where appropriate subject to conditions (which are complied with), and has not withdrawn that authorisation: reg 12(5). As to the Secretary of State see PARA 3 note 3 ante.

7 'Supply', in relation to a medical device, means the supply of, or the offer or agreement to supply, the device, or the exposure or possession for supply of the device: ibid reg 2(1).

8 Ibid reg 8(2)(a).

9 Ibid reg 8(2)(b).

10 Ie set out in EC Council Directive 93/42 (OJ L169, 12.7.1993, p 1) Annex I: Medical Devices Regulations 2002, SI 2002/618, regs 5(2), 8(2). See also note 5 supra.

11 Ibid reg 8(2). This provision is expressed to be subject to reg 12: see note 6 supra.

12 See ibid regs 10, 12, 14.

13 See ibid reg 11. As to procedures for affixing a CE marking to general medical devices see reg 13.

14 See ibid reg 15. For these purposes, 'custom-made device' means a relevant device that is:

80 (1) manufactured specifically in accordance with a written prescription of a duly qualified medical practitioner or a professional user which gives, under his responsibility, specific characteristics as to its design; and

81 (2) intended for the sole use of a particular patient,

but does not include a mass-produced product which needs to be adapted to meet the specific requirements of the medical practitioner or professional user: reg 5(1).

15 See ibid reg 16. For the meaning of 'United Kingdom' see PARA 7 note 3 ante. As to the fees payable in respect of such matters see reg 56-58.

16 See ibid reg 17 (amended by SI 2003/1697).

17 See the Medical Devices Regulations 2002, SI 2002/618, reg 18 (amended by SI 2003/1697).

18 See the Medical Devices Regulations 2002, SI 2002/618, reg 19. As to the fee payable in respect of the provision of such information see regs 53, 57, 58.

UPDATE

232 General medical devices

TEXT AND NOTES 1-11--Where a hazard exists, devices which are also machinery must also meet the essential health and safety requirements set out in European Parliament and EC Council Directive 2006/42 (OJ L157, 9.6.2006, p 24) Annex I to the extent to which those requirements are more specific than the essential requirements in Directive 93/42: SI 2002/618 reg 8(3) (added by SI 2008/2936 with effect from 21 March 2010). 'Hazard' means a potential source of injury or damage to health; and 'machinery' has the meaning given to it by Directive 2006/42 art 2(a): SI 2002/618 reg 2(1) (definitions added by SI 2008/2936 with effect from 21 March 2010).

NOTE 5--SI 2002/618 reg 9 amended: SI 2008/2936 (with effect from 21 March 2010).

NOTE 12--SI 2002/618 reg 14 amended: SI 2008/2936 (with effect from 21 March 2010).

NOTES 14, 15--SI 2008/618 regs 15, 16; and definition of 'custom-made device' in reg 5(1) amended: SI 2008/2936 (with effect from 21 March 2010).

NOTE 15--SI 2002/618 reg 56 amended: SI 2007/803, SI 2008/530.

NOTE 17--SI 2002/618 reg 18 further amended: SI 2008/2936 (with effect from 21 March 2010).

NOTE 18--SI 2002/618 reg 19 amended: SI 2008/2936 (with effect from 21 March 2010).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/2. MEDICAL DEVICES/233. Active implantable medical devices.

233. Active implantable medical devices.

No person¹ may place on the market² or put into service³ a relevant device⁴ unless that device meets those essential requirements⁵ which apply to it⁶; and no person may supply⁷ a relevant device if that supply is also a placing on the market or putting into service of that device⁸, or in circumstances where that device has also been placed on the market or put into service⁹, unless that device meets those essential requirements¹⁰ which apply to it¹¹.

Restrictions are imposed: (1) on the placing on the market, putting into service, and supply of active implantable medical devices unless the device, packaging or instructions for use bear a CE marking¹²; (2) on the use of misleading markings¹³; and (3) on the affixing of a CE marking to such devices¹⁴. Restrictions are also placed on the supply of custom-made devices¹⁵, and on the supply of active implantable medical devices for the purposes of a clinical investigation in the United Kingdom¹⁶. Manufacturers of active implantable medical devices must follow certain procedures¹⁷, and provision is made for conformity assessments of such devices¹⁸.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 For the meaning of 'placing on the market' see PARA 231 note 1 ante.

3 For the meaning of 'putting into service' see PARA 232 note 3 ante.

4 'Relevant device' means active implantable medical devices and accessories to such devices, except for devices that come within the scope of EC Council Directive 90/385 (OJ L189, 20.7.1990, p 17) on the approximation of the laws of the member states relating to active implantable medical devices (as amended) and another Directive ('the other Directive') issued by one or more of the institutions of the Community, if: (1) the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it; and (2) the manufacturer chooses to follow the set of arrangements in the other Directive: Medical Devices Regulations 2002, SI 2002/618, regs 2(1), 20(1), 21. 'Active implantable medical device' means a medical device which:

82 (a) relies for its functioning on a source of electrical energy or a source of power other than that generated directly by the human body or by gravity; and

83 (b) is intended to be totally or partially introduced into the human body (whether surgically or medically, including being introduced into a natural orifice) and which is intended to remain in the human body after completion of the surgical or medical procedure during which it is introduced,

even if it is intended to administer a medicinal product or incorporates as an integral part a substance which, if used separately, would be a medicinal product: reg 2(1). For the meanings of 'the Community' and 'manufacturer' see PARA 231 note 1 ante; for the meaning of 'medical device' see PARA 231 ante; and for the meaning of 'medicinal product' see PARA 231 note 2 ante.

5 See set out in EC Council Directive 90/385 (OJ L189, 20.7.1990, p 17) Annex 1: Medical Devices Regulations 2002, SI 2002/618, regs 20(2), 22(1) (reg 20(2) amended by SI 2003/1697). As to the determination of the compliance of active implantable medical devices with relevant essential requirements see the Medical Devices Regulations 2002, SI 2002/618, reg 23.

6 Ibid reg 22(1). A relevant device being shown at a trade fair, exhibition, demonstration or similar gathering is not being placed on the market or put into service if a visible sign clearly indicates that the device or product cannot be marketed or put into service until it complies with the requirements of EC Council Directive 90/385 (OJ L189, 20.7.1990, p 17) or the Medical Devices Regulations 2002, SI 2002/618 (as amended): reg 26(1). Regulation 22 does not apply where, following a duly justified request and in the interests of the protection of health, the Secretary of State has authorised, where appropriate for a specified period, the placing on the market or putting into service of a particular relevant device or relevant devices of a particular class or description without a CE marking, where appropriate subject to conditions (which are complied with), and has

not withdrawn that authorisation: reg 26(3). For the meaning of 'CE marking' see PARA 232 note 4 ante. As to the Secretary of State see PARA 3 note 3 ante.

7 For the meaning of 'supply' see PARA 232 note 7 ante.

8 Medical Devices Regulations 2002, SI 2002/618, reg 22(2)(a).

9 Ibid reg 22(2)(b).

10 Ie set out in EC Council Directive 90/385 (OJ L189, 20.7.1990, p 17) Annex 1: Medical Devices Regulations 2002, SI 2002/618, regs 20(2), 22(2) (reg 20(2) as amended: see note 5 supra). See also note 5 supra.

11 Medical Devices Regulations 2002, SI 2002/618, reg 22(2). This provision is expressed to be subject to reg 26: see note 6 supra.

12 See ibid regs 24(1)-(4), 26.

13 See ibid regs 24(5), 26.

14 See ibid reg 25. As to procedures for affixing a CE marking to active implantable medical devices see reg 27.

15 See ibid reg 28. For these purposes, 'custom-made device' means an active implantable medical device that is manufactured specifically in accordance with a medical specialist's written prescription which gives, under his responsibility, specific characteristics as to its design, and which is intended to be used only for a particular patient: reg 20(1). For the meaning of 'medical specialist' see PARA 231 note 1 ante.

16 See ibid reg 29. As to the fees payable in respect of such matters see regs 56-58.

17 See ibid reg 30.

18 See ibid reg 31.

UPDATE

233 Active implantable medical devices

NOTE 4--Where a hazard exists, devices which are also machinery must also meet the essential health and safety requirements set out in Annex I to that Directive (it is submitted that the phrase 'that Directive' refers to EC Council Directive 2006/42) to the extent to which those requirements are more specific than the essential requirements in Directive 90/385 Annex I: SI 2002/618 reg 21(2) (added by SI 2008/2936 with effect from 21 March 2010). As to the meaning of 'hazard' and 'machinery' see PARA 232. Where an active implantable medical device is intended to administer a medicinal product, that device is governed by Directive 90/385 without prejudice to the provisions of Directive 2001/83: reg 21(3) (added by SI 2008/2936 with effect from 21 March 2010).

NOTES 16-18--SI 2002/618 regs 29-31 amended: SI 2008/2936 (with effect from 21 March 2010).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/2. MEDICAL DEVICES/234. In vitro diagnostic medical devices.

234. In vitro diagnostic medical devices.

No person¹ may place on the market² or put into service³ a relevant device⁴ unless that device meets those essential requirements⁵ which apply to it⁶; and no person may supply⁷ a relevant device if that supply is also a placing on the market or putting into service of that device⁸, or in circumstances where that device has been placed on the market or put into service⁹, unless that device meets those essential requirements¹⁰ which apply to it¹¹. Nor may any person:

207 (1) put into service a relevant device¹²;

208 (2) supply a relevant device if that supply is also a putting into service of that device¹³, or in circumstances where that device has been placed on the market or put into service¹⁴,

which is not ready for use¹⁵. No person may supply a device for performance evaluation¹⁶, if that supply is also a making available of the device, unless certain conditions are met¹⁷.

Restrictions are imposed: (a) on the placing on the market, putting into service, and supply of in vitro diagnostic medical devices unless the device, packaging or instructions for use bear a CE marking¹⁸; (b) on the use of misleading markings¹⁹; and (c) on the affixing of a CE marking to such devices²⁰. Manufacturers of in vitro diagnostic medical devices must follow certain procedures²¹, and provision is made for conformity assessments of such devices²². Persons placing in vitro diagnostic medical devices on the market must provide the Secretary of State with prescribed information²³.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 For the meaning of 'placing on the market' see PARA 231 note 1 ante.

3 For the meaning of 'putting into service' see PARA 232 note 3 ante.

4 'Relevant device' means in vitro diagnostic medical devices and accessories to such devices, except for: (1) products manufactured and used within the same health institution and either on the premises of their manufacture or on premises in the immediate vicinity without having been transferred to another legal entity (Medical Devices Regulations 2002, SI 2002/618, reg 33(1)(a)); and (2) devices that come within the scope of EC Parliament and Council Directive 98/79 (OJ L331, 7.12.1998, p 1) on in vitro diagnostic medical devices and another Directive ('the other Directive') issued by one or more of the institutions of the Community, if the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it, and the manufacturer chooses to follow the set of arrangements in the other Directive (Medical Devices Regulations 2002, SI 2002/618, regs 2(1), 33(1)(b)). 'In vitro diagnostic medical device' means a medical device which:

84 (a) is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, equipment or system, whether used alone or in combination; and

85 (b) is intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information:

18. (i) concerning a physiological or pathological state;
18

19. (ii) concerning a congenital abnormality;
19

20. (iii) to determine the safety and compatibility of donations, including blood and tissue donations, with potential recipients; or
20

21. (iv) to monitor therapeutic measures,
21

and includes a specimen receptacle but not a product for general laboratory use, unless that product, in view of its characteristics, is specifically intended by its manufacturer to be used for in vitro diagnostic examination: reg 2(1). 'Accessory' means an article intended specifically by its manufacturer to be used together with an in vitro diagnostic medical device to enable that device to be used in accordance with its intended purpose, which is not itself an in vitro diagnostic medical device, an invasive sampling medical device, or a medical device which is directly applied to the human body for the purpose of obtaining a specimen: reg 32(1). For the meanings of 'the Community' and 'manufacturer' see PARA 231 note 1 ante. For the meaning of 'medical device' see PARA 231 ante. For the meaning of 'tissue' see PARA 231 note 9 ante. 'Specimen receptacle' means a medical device which (whether vacuum-type or not) is specifically intended by its manufacturer to be used for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination: reg 2(1).

Part IV (regs 32-44) (as amended) does not apply before 7 December 2005 in respect of a device put into service which is:

86 (A) an in vitro diagnostic medical device without a CE marking; or

87 (B) a device for performance evaluation (see note 16 infra) and the manufacturer or his authorised representative does not indicate, directly or indirectly, that it is a device which is subject to the provisions of the regulations,

if the device satisfies the requirements of the laws of that part of the United Kingdom in which it is put into service as in force on 7 December 1998: reg 4(4). For the meaning of 'CE marking' see PARA 232 note 4 ante. For the meaning of 'United Kingdom' see PARA 7 note 3 ante. 'Authorised representative' means a person established within the Community or in a state which is a party to an association agreement who, explicitly designated by the manufacturer, acts for the manufacturer and may be addressed by authorities and bodies in the Community instead of the manufacturer; and 'association agreement' means an agreement, listed in Sch 1, establishing an association between the European Communities and their member states, on the one part, and another state on the other part (a 'state which is a party to an association agreement') on conformity assessment and acceptance of industrial products: reg 2(1). For the meaning of 'member state' see the European Communities Act 1972 s 1(2), Sch 1 Pt II; and the Interpretation Act 1978 s 5, Sch 1. As to provisions relating to the designation of authorised representatives see the Medical Devices Regulations 2002, SI 2002/618, reg 60.

5 le set out in EC Parliament and Council Directive 98/79 (OJ L331, 7.12.1998, p 1) Annex I: Medical Devices Regulations 2002, SI 2002/618, regs 32(2), 34(1) (reg 32(2) amended by SI 2003/1697). As to the determination of the compliance of in vitro diagnostic medical devices with relevant essential requirements see the Medical Devices Regulations 2002, SI 2002/618, reg 35.

6 Ibid reg 34(1). A relevant device being shown at a trade fair, exhibition, scientific gathering or technical gathering is not being placed on the market or put into service if the device is not used on any specimen taken from the participants, and a visible sign clearly indicates that the device cannot be marketed or put into service until it complies with the requirements of EC Parliament and Council Directive 98/79 (OJ L331, 7.12.1998, p 1) or the Medical Devices Regulations 2002, SI 2002/618 (as amended): reg 39(1). Regulations 34, 36, 38 (see the text to notes 12-15, 18-19 infra) do not apply where, following a duly justified request and in the interests of the protection of health, the Secretary of State has authorised, where appropriate for a specified period, the placing on the market or putting into service of a particular relevant device or relevant devices of a particular class or description without a CE marking, where appropriate subject to conditions (which are complied with), and has not withdrawn that authorisation: reg 39(2). As to the Secretary of State see PARA 3 note 3 ante.

7 For the meaning of 'supply' see PARA 232 note 7 ante.

8 Medical Devices Regulations 2002, SI 2002/618, reg 34(2)(a).

9 Ibid reg 34(2)(b).

10 le set out in EC Parliament and Council Directive 98/79 (OJ L331, 7.12.1998, p 1) Annex I: Medical Devices Regulations 2002, SI 2002/618, regs 32(2), 34(2) (reg 32(2) as amended: see note 5 supra). See also note 5 supra.

11 Ibid reg 34(2). This provision is expressed to be subject to reg 39: see note 6 supra.

12 Ibid reg 38(a).

- 13 Ibid reg 38(b)(i).
- 14 Ibid reg 38(b)(ii).
- 15 Ibid reg 38. This provision is expressed to be subject to reg 39: see note 6 supra.
- 16 'Device for performance evaluation' means a product which is intended by its manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analysis or in other appropriate environments outside his own premises: *ibid* reg 2(1).
- 17 Ibid reg 43. As to the conditions see reg 43(a)-(c). The requirements of Pt IV (as amended) in respect of devices for performance evaluation do not apply in respect of: (1) products manufactured and used only within the same health institution and either on the premises of their manufacture or on premises in the immediate vicinity without having been transferred to another legal entity (reg 33(2)(a)); and (2) devices that come within the scope of EC Parliament and Council Directive 98/79 (OJ L331, 7.12.1998, p 1) and another Directive ('the other Directive') issued by one or more of the institutions of the Community, if the other Directive includes a provision allowing the manufacturer of the device to choose, during a transitional period that has not ended, which set of arrangements applies to it, and the manufacturer chooses to follow the set of arrangements in the other Directive (Medical Devices Regulations 2002, SI 2002/618, reg 33(2)(b)).
- 18 See *ibid* reg 36(1)-(4), 37. Regulation 36 is expressed to be subject to reg 39: see note 6 supra.
- 19 See *ibid* reg 36(5). This provision is expressed to be subject to reg 39: see note 6 supra.
- 20 See *ibid* reg 40.
- 21 See *ibid* reg 41.
- 22 See *ibid* reg 42.
- 23 See *ibid* reg 44. As to the fee payable in respect of the provision of such information see regs 53, 57, 58.

UPDATE

234 In vitro diagnostic medical devices

NOTE 4--In the definition of 'authorised representative', words 'with regard to the latter's obligation under EC Council Directive 90/385, EC Council Directive 93/42 and European Parliament and EC Council Directive 98/79' added: SI 2002/618 reg 2(1) (amended by SI 2008/2936 with effect from 21 March 2010). SI 2002/618 reg 60 amended: SI 2008/2936 (with effect from 21 March 2010).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/2. MEDICAL DEVICES/235. Notified bodies and conformity assessment bodies.

235. Notified bodies and conformity assessment bodies.

The Secretary of State¹ may designate² any corporate or other body as a body which is to carry out any of the tasks of a notified body³, and, if he so designates a body, he must designate the tasks which it is to carry out⁴. The Secretary of State may designate for the purposes of the mutual recognition agreements any corporate or other body as a body which is to carry out any of the tasks of a European Community conformity assessment body, and, if he so designates a body, he must designate the tasks which it is to carry out⁵.

Restrictions are placed on the affixing of a notified body or conformity assessment body number to a medical device⁶, to the supply⁷ of a medical device which has affixed to it a notified body or conformity assessment body number⁸, and to the provision of information comprising a notified body or conformity assessment body number on a medical device⁹. Restrictions are also placed on the affixing of the CE marking¹⁰ for a medical device to a product which is not a medical device¹¹, the supply of a product so marked¹², and the provision of information comprising a CE marking for a medical device if the product is not a medical device¹³.

1 As to the Secretary of State see PARA 3 note 3 ante.

2 See for the purposes of EC Council Directive 90/385 (OJ L189, 20.7.1990, p 17) art 11, EC Council Directive 93/42 (OJ L169, 12.7.1993, p 1) art 16 or EC Parliament and Council Directive 98/79 (OJ L331, 7.12.1998, p 1) art 15.

3 'Notified body' means a body authorised in accordance with the Medical Devices Regulations 2002, SI 2002/618, Pt V (regs 44A-51) (as amended), or the Medical Devices Directives to carry out tasks of a notified body or the importing party under the Medical Devices Directives or the mutual recognition agreements in respect of a conformity assessment procedure: reg 2(1). 'The Medical Devices Directives' means EC Council Directive 90/385 (OJ L189, 20.7.1990, p 17), EC Council Directive 93/42 (OJ L169, 12.7.1993, p 1) read with EC Commission Directive 2003/32 (OJ L105, 26.4.2003, p 18), and EC Parliament and Council Directive 98/79 (OJ L331, 7.12.1998, p 1); Medical Devices Regulations 2002, SI 2002/618, reg 2(1). 'Mutual recognition agreements' means the agreements, listed in Sch 2, concluded between the European Community and states which are not part of the European Community on matters including the conditions under which each party will accept or recognise the results of the conformity assessment procedures undertaken by the other party's designated bodies: reg 2.

4 Ibid reg 45(1). As to the conditions relating to the appointment of such bodies see reg 45(2)-(8) (amended by SI 2003/1697). As to general matters relating to UK notified bodies see the Medical Devices Regulations 2002, SI 2002/618, reg 47 (amended by SI 2003/1697). As to the choice by a manufacturer of a notified body see the Medical Devices Regulations 2002, SI 2002/618, reg 46. For the meaning of 'manufacturer' see PARA 231 note 1 ante. As to fees chargeable by notified bodies see reg 49. As to the fees payable in connection with the designation of notified bodies and certain other matters relating to such bodies see regs 54, 57, 58 (reg 54 amended by SI 2003/1697).

5 Medical Devices Regulations 2002, SI 2002/618, reg 48. As to the fees payable in connection with the designation of such bodies and certain other matters relating to such bodies see regs 55, 57, 58.

6 See ibid reg 50(1)(a). For the meaning of 'medical device' see PARA 231 ante.

7 For the meaning of 'supply' see PARA 232 note 7 ante.

8 See the Medical Devices Regulations 2002, SI 2002/618, regs 50(1)(b), (3).

9 See ibid reg 50(2).

10 For the meaning of 'CE marking' see PARA 232 note 4 ante.

11 Medical Devices Regulations 2002, SI 2002/618, reg 51(1)(a).

12 See *ibid* reg 51(1)(b).

13 See *ibid* reg 51(2).

UPDATE

235 Notified bodies and conformity assessment bodies

NOTE 4--SI 2002/618 reg 47 further amended: SI 2008/2936 (with effect from 21 March 2010). SI 2002/618 reg 54 amended: SI 2007/803, SI 2008/530.

NOTE 5--SI 2002/618 reg 55 amended: SI 2007/803, SI 2008/530.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/2. MEDICAL DEVICES/236. Enforcement.

236. Enforcement.

The regulations¹ relating to medical devices² are to be regarded for all purposes relating to enforcement, whether by criminal proceedings, notices or otherwise, as safety regulations³ made under the Consumer Protection Act 1987⁴. The Secretary of State⁵ is responsible for the enforcement of the safety provisions⁶ relating to relevant devices⁷ or devices for performance evaluation⁸; but, in relation to devices which are consumer goods⁹, each weights and measures authority in Great Britain¹⁰ must, concurrently with the Secretary of State, enforce the provisions in relation to such devices¹¹.

Except in the case of a device which in the opinion of an enforcement authority¹² is likely to compromise the health or safety of any person, where an enforcement authority has reasonable grounds for suspecting that a relevant device or a device for performance evaluation is a device in respect of which there is a failure to comply with the regulations, that authority may serve upon the manufacturer or his authorised representative a notice¹³ requiring him to secure that the device conforms to specified provisions within a specified period¹⁴, or to provide evidence within that period to the satisfaction of the enforcement authority that all the provisions have been complied with in so far as they relate to that device¹⁵, and warning the person¹⁶ on whom the notice is served that unless the requirements of the notice are met, further action may be taken¹⁷.

Where an enforcement authority is of the opinion that, in order to protect the health or safety of any individual or of individuals of any class or description, it is necessary to restrict the availability of a particular medical device, a particular accessory to such a device or a particular device for performance evaluation¹⁸, or medical devices, accessories to such devices or devices for performance evaluation of a particular class or description¹⁹, it may serve on any person a restriction notice including such directions restricting the availability of that device or those devices as appear to it to be necessary in order to protect the health or safety of that individual or individuals of that class or description²⁰.

Any decision taken by a UK notified body²¹, the Secretary of State or any other enforcement authority to withdraw a device from the market, or to prevent or restrict a device being placed on the market²², put into service²³ or made available, must be notified without delay to the person responsible for marketing the device, placing it on the market, putting it into service or making it available²⁴. Except in cases where urgent action is justified, in particular by public health requirements, if a notified body, the Secretary of State or any other enforcement authority is considering making such a decision, it or he must give the manufacturer or his authorised representative an opportunity to make representations to it or him before the decision is taken²⁵.

In respect of an offence relating to a contravention of the regulations²⁶, a magistrates' court may try any information laid within 12 months from the time when the offence was committed²⁷.

1 Ie the Medical Devices Regulations 2002, SI 2002/618 (as amended).

2 For the meaning of 'medical device' see PARA 231 ante.

3 Ie as defined in the Consumer Protection Act 1987: see SALE OF GOODS AND SUPPLY OF SERVICES vol 41 (2005 Reissue) PARA 539.

4 See the Medical Devices Regulations 2002, SI 2002/618, reg 61(1) (amended by SI 2003/1400).

5 As to the Secretary of State see PARA 3 note 3 ante. The Secretary of State must perform, as respects the United Kingdom, the functions of the member state under EC Council Directive 90/385 (OJ L189, 20.7.1990, p 17) art 8, EC Council Directive 93/42 (OJ L169, 12.7.1993, p 1) art 10 and EC Parliament and Council Directive 98/79 (OJ L331, 7.12.1998, p 1) art 11(1)-(3): Medical Devices Regulations 2002, SI 2002/618, reg 65. For the meaning of 'United Kingdom' see PARA 7 note 3 ante. For the meaning of 'member state' see the European Communities Act 1972 s 1(2), Sch 1 Pt II; and the Interpretation Act 1978 s 5, Sch 1. As to the establishment of the medicines and healthcare products regulatory agency trading fund in connection with certain operations of the Department of Health in relation to medical devices see the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003, SI 2003/1076 (amended by SI 2005/2061). As to government trading funds generally see CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARA 743 et seq.

6 The duty imposed by the Consumer Protection Act 1987 s 27(1) (see SALE OF GOODS AND SUPPLY OF SERVICES vol 41 (2005 Reissue) PARA 555) is transferred to the Secretary of State: see the Medical Devices Regulations 2002, SI 2002/618, reg 61(2).

7 'Relevant device' means a device that is a relevant device for the purposes of ibid Pt II, III or IV (see PARAS 232 note 4, 233 note 4, 234 note 4 ante): reg 59.

8 See ibid reg 61(2). For the meaning of 'device for performance evaluation' see PARA 234 note 16 ante. The powers conferred by the Consumer Protection Act 1987 s 13 to serve prohibition notices and notices to warn (see SALE OF GOODS AND SUPPLY OF SERVICES vol 41 (2005 Reissue) PARA 544) are exercisable in relation to non-conforming devices as they are exercisable in relation to relevant goods which the Secretary of State considers are unsafe (as well as being exercisable in relation to goods considered unsafe by the Secretary of State); and, in relation to non-conforming devices, the Consumer Protection Act 1987 Sch 2 (see SALE OF GOODS AND SUPPLY OF SERVICES vol 41 (2005 Reissue) PARA 545) has effect as if references to goods being unsafe or safe were references to relevant devices being or not being non-conforming devices: Medical Devices Regulations 2002, SI 2002/618, reg 61(7). 'Non-conforming devices' means:

- 88 (1) relevant devices which, whether or not the Secretary of State considers them unsafe, are devices with or that require a CE marking which he considers to be devices:
- 22. (a) which do not conform as respects a relevant essential requirement (reg 61(8)(a)(i)); or
22
- 23. (b) to which a CE marking has or should have been applied following a conformity assessment procedure set out in the Medical Devices Directives, and the manufacturer or his authorised representative has failed to comply with his obligations under that procedure, or they do not conform to the design or type described in any certificate granted as a result of that procedure (reg 61(8)(a)(ii)); or
23
- 89 (2) devices for performance evaluation which, whether or not the Secretary of State considers them unsafe, are devices in respect of which there is a failure to comply with the Medical Devices Regulations 2002, SI 2002/618 (as amended) (reg 61(8)(b)).

For the meaning of 'CE marking' see PARA 232 note 4 ante. For the meaning of 'Medical Devices Directives' see PARA 235 note 3 ante. For the meaning of 'manufacturer' see PARA 231 note 1 ante. For the meaning of 'authorised representative' see PARA 234 note 4 ante.

9 'Consumer goods' means any goods which are ordinarily intended for private use or consumption: Medical Devices Regulations 2002, SI 2002/618, reg 61(7A) (added by SI 2005/2909).

10 As to weights and measures authorities see SALE OF GOODS AND SUPPLY OF SERVICES vol 41 (2005 Reissue) PARA 398; WEIGHTS AND MEASURES vol 50 (2005 Reissue) PARA 20. For the meaning of 'Great Britain' see PARA 7 note 3 ante.

11 See the Medical Devices Regulations 2002, SI 2002/618, reg 61(3) (amended by SI 2005/2909). However, the powers of an enforcement authority to serve restriction notices under the Medical Devices Regulations 2002, SI 2002/618, reg 63 (see the text to notes 18-20 infra) are only exercisable by the Secretary of State: reg 61(4). Each weights and measures authority must give immediate notice to the Secretary of State of certain actions taken by it: see reg 61(5).

12 For the meaning of 'enforcement authority' see the Consumer Protection Act 1987 s 45(1); and SALE OF GOODS AND SUPPLY OF SERVICES vol 41 (2005 Reissue) PARA 549.

13 As to the matters to be stated in the notice see the Medical Devices Regulations 2002, SI 2002/618, reg 62(1)(a)-(c), (3). As to the effect of the notice see reg 62(2).

14 Ibid reg 62(1)(d)(i).

15 Ibid reg 62(1)d)(ii).

16 For the meaning of 'person' see PARA 21 note 7 ante.

17 See the Medical Devices Regulations 2002, SI 2002/618, reg 62(1)(e).

18 Ibid reg 63(1)(a).

19 Ibid reg 63(1)(b).

20 Ibid reg 63(1). This provision does not apply to active implantable medical devices or to accessories to such devices: reg 63(2). See also note 11 supra. For the meaning of 'active implantable medical device' see PARA 233 note 4 ante. The enforcement authority responsible for serving a restriction notice may, in appropriate circumstances, withdraw the notice: reg 63(3). A direction in a restriction notice that has not been withdrawn by an enforcement authority or set aside by court order is a safety provision for the purposes of the Consumer Protection Act 1987 ss 14-17 (s 17 as amended) (suspension notices and forfeiture: see SALE OF GOODS AND SUPPLY OF SERVICES vol 41 (2005 Reissue) PARAS 549-553); Medical Devices Regulations 2002, SI 2002/618, reg 63(4). As to orders setting aside restriction notices see reg 63(5), (6).

21 'UK notified body' is to be construed in accordance with ibid reg 45 (see PARA 235 ante): reg 2(1).

22 For the meaning of 'placing on the market' see PARA 231 note 1 ante.

23 For the meaning of 'putting into service' see PARA 232 note 3 ante.

24 Medical Devices Regulations 2002, SI 2002/618, reg 64(1). As to the information to be included in such a notice see reg 64(1)(a)-(c).

25 Ibid reg 64(2).

26 Is an offence committed under the Consumer Protection Act 1987 s 12: see SALE OF GOODS AND SUPPLY OF SERVICES vol 41 (2005 Reissue) PARA 540.

27 Medical Devices Regulations 2002, SI 2002/618, reg 61(6)(a). As to magistrates courts see MAGISTRATES.

UPDATE

236 Enforcement

NOTE 20--SI 2002/618 reg 63(2) revoked: SI 2008/2936 (with effect from 21 March 2010).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(1) INTRODUCTION/237. Control of drugs.

3. CONTROLLED DRUGS

(1) INTRODUCTION

237. Control of drugs.

The principal statute which is concerned with the control of drugs which are dangerous or otherwise harmful is the Misuse of Drugs Act 1971¹. These drugs are listed as controlled drugs and are classified according to their relative harmfulness². The Act imposes restrictions on the importation, exportation, production, supply and possession of controlled drugs³, and makes the cultivation of the cannabis plant an offence⁴. An occupier of premises is prohibited from allowing them to be used for such purposes as producing or supplying a controlled drug and smoking cannabis or opium⁵. The smoking of opium and other activities relating to opium are prohibited⁶.

The Secretary of State⁷ is given powers to prevent the misuse of controlled drugs. He may make regulations to prevent misuse⁸, direct special precautions to be taken for safe custody⁹, and restrict prescribing and supply by persons who have been convicted of offences or have contravened regulations or licences or have otherwise acted irresponsibly¹⁰. He may obtain information from doctors and pharmacists¹¹. Regulations may exclude in prescribed cases the application of a provision creating an offence, may extend the investigation procedure to other cases, and may apply the provisions of the Act and regulations to servants or agents of the Crown¹².

The Secretary of State may by order¹³ repeal or amend any provision in any local Act¹⁴, and may conduct or assist in conducting research into any matter relating to the misuse of dangerous or otherwise harmful drugs¹⁵. The expenses he incurs with Treasury consent for the purposes of such research are to be defrayed out of money provided by Parliament¹⁶, as are any expenses he incurs under or in consequence of any other provision of the Misuse of Drugs Act 1971¹⁷. The Secretary of State may also, with the consent of the Treasury, pay such grants to such persons¹⁸ as he considers appropriate in connection with measures intended to combat or deal with drug trafficking or the misuse of drugs¹⁹ or to deal with consequences of the misuse of drugs²⁰.

The Proceeds of Crime Act 2002²¹ makes provision for the recovery of the proceeds of crime, including drug trafficking²², introducing a range of orders designed to facilitate this task, including confiscation orders, restraint orders and property freezing orders²³. The Act also creates offences relating to money laundering²⁴. The Criminal Justice (International Co-operation) Act 1990 contains measures designed to facilitate the detection of drug traffickers and the confiscation of the proceeds of drug trafficking²⁵. The Crime (International Co-operation) Act 2003 makes provision for international assistance in criminal matters²⁶. Under the Drugs Act 2005 the police are given powers in respect of the assessment of persons suspected of offences relating to the use of Class A controlled drugs²⁷; and by the Anti-Social Behaviour Act 2003 the police are given powers to apply to the magistrates' court for an order for the closure of premises they believe to be used in connection with the unlawful use, production or supply of a Class A controlled drug, where the use of the premises is associated with the occurrence of disorder or serious nuisance to members of the public²⁸.

¹ The Misuse of Drugs Act 1971, which repealed the Drugs (Prevention of Misuse) Act 1964 and the Dangerous Drugs Acts 1965 and 1967 (see the Misuse of Drugs Act 1971 s 39(2), Sch 6), is based, in part, upon

the Single Convention on Narcotic Drugs (New York, 30 March to 1 August 1961; TS 34 (1965); Cmnd 2631), amended by Protocol (Geneva, 25 March to 31 December 1972; TS 23 (1979); Cmnd 7466). As to the application of the Single Convention on Narcotic Drugs to the Misuse of Drugs Act 1971 see PARA 260 post.

2 See the Misuse of Drugs Act 1971 s 2, Sch 2; and PARAS 238-241 post. For the meaning of 'controlled drug' see PARA 238 post.

3 See *ibid* ss 3-5; and PARAS 248-252 post.

4 See *ibid* s 6; and PARA 254 post.

5 See *ibid* s 8; and PARA 255 post.

6 See *ibid* s 9; and PARA 257 post.

7 As to the Secretary of State see PARA 3 note 3 ante.

8 See the Misuse of Drugs Act 1971 s 10; and PARA 263 post.

9 See *ibid* s 11; and PARA 265 post.

10 See *ibid* ss 12, 13; and PARAS 272-273 post.

11 See *ibid* s 17; and PARA 268 post.

12 See *ibid* ss 22, 31; and PARAS 242-243 post. Crown immunity from the effect of the Misuse of Drugs Act 1971 in respect of the national health service was removed as from 1 April 1991: see the National Health Service and Community Care Act 1990 s 60; and the National Health Service and Community Care Act 1990 (Commencement No 1) Order 1990, SI 1990/1329, Sch 3. A visiting force or headquarters, members of such a force or headquarters, persons employed in the service of such a force, and property used for the purposes of such a force or headquarters are exempt from the operation of the Misuse of Drugs Act 1971 to the extent that Crown immunity exempts home forces from it: see the Visiting Forces and International Headquarters (Application of Law) Order 1999, SI 1999/1736, art 12(1), Sch 5; and ARMED FORCES vol 2(2) (Reissue) PARA 142.

13 Such an order is to be made by statutory instrument which is subject to annulment in pursuance of a resolution of either House of Parliament: Misuse of Drugs Act 1971 s 39(3). As to the annulment of statutory instruments see STATUTES vol 44(1) (Reissue) PARA 1516.

14 *Ibid* s 39(3). This includes an Act confirming a provisional order, or a provision in any instrument in the nature of a local enactment under any Act, where it appears to the Secretary of State that such a provision is inconsistent with, or has become unnecessary or requires modification in consequence of, any provision of the Misuse of Drugs Act 1971: s 39(3). At the date at which this volume states the law, no such order had been made.

15 *Ibid* s 32.

16 *Ibid* s 35(b). As to the Treasury see CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARAS 512-517.

17 *Ibid* s 35(a).

18 For the meaning of 'person' see PARA 21 note 7 ante.

19 Criminal Justice Act 1993 s 73(1)(a).

20 *Ibid* s 73(1)(b). Any such grant may be made subject to such conditions as the Secretary of State may, with the agreement of the Treasury, see fit to impose (s 73(2)); and any payments must be made out of money provided by Parliament (s 73(3)).

21 As to the Proceeds of Crime Act 2002 generally see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARA 789 et seq; CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(4) (2006 Reissue) PARA 2147 et seq; and SENTENCING AND DISPOSITION OF OFFENDERS vol 92 (2010) PARAS 390 et seq.

22 See *ibid* s 75, Sch 2.

23 See *ibid* Pt 2 (ss 6-91) (as amended), Pt 5 (ss 240-316) (as amended). The confiscation procedures of the Drug Trafficking Offences Act 1986 from which those under the Proceeds of Crime Act 2002 derive were enacted in response to the decision of the House of Lords in *R v Cuthbertson* [1981] AC 470, [1980] 2 All ER 401, HL (conspiracy to produce and supply a controlled drug, contrary to the Misuse of Drugs Act 1971 s 4; the

appellants successfully argued in the House of Lords that the forfeiture order under the Act applied only to tangible things, not to choses or things in action and other intangibles).

24 See the Proceeds of Crime Act 2002 Pt 7 (ss 327-340) (as amended).

25 See the Criminal Justice (International Co-operation) Act 1990 Pt II (ss 12-24) (as amended); and CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARAS 772-773, 780.

26 As to the Crime (International Co-operation) Act 2003 see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARAS 772-773, 780; CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2), (3) (2006 Reissue) PARA 1411.

27 See the Drugs Act 2005 Pt 3 (ss 9-19) (not yet in force); CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARA 1031 et seq. At the date at which this volume states the law, these provisions had yet to be brought into effect.

28 See the Anti-Social Behaviour Act 2003 Pt 1 (ss 1-9); and PARA 256 post.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

237 Control of drugs

NOTES--Certain functions under provisions mentioned in this paragraph are 'relevant functions' for the purposes of the Regulatory Enforcement and Sanctions Act 2008 s 4, Sch 3, see LOCAL GOVERNMENT vol 69 (2009) PARA 733.

NOTE 12--1990 Act s 60 amended: National Health Service (Consequential Provisions) Act 2006 Sch 1 para 131.

NOTE 27--2005 Act ss 9, 12, 18, 19 now in force; ss 11, 15-17 in force for certain purposes: see SI 2005/3053.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(1) INTRODUCTION/238. Controlled drugs.

238. Controlled drugs.

'Controlled drug' means any substance or product for the time being specified in Part I, Part II or Part III of Schedule 2 to the Misuse of Drugs Act 1971¹. 'Class A drug'², 'Class B drug'³ and 'Class C drug'⁴ mean any of the substances and products for the time being specified respectively in Part I, Part II and Part III of that Schedule⁵.

Her Majesty may by Order in Council⁶ make such amendments to that Schedule⁷ as may be requisite for the purpose of adding any substance or product to, or removing any substance or product from, any of those Parts⁸.

1 Misuse of Drugs Act 1971 s 2(1)(a).

2 As to Class A drugs see PARA 239 post.

3 As to Class B drugs see PARA 240 post.

4 As to Class C drugs see PARA 241 post.

5 Misuse of Drugs Act 1971 s 2(1)(b).

6 No recommendation may be made to Her Majesty to make such an order unless a draft has been laid before Parliament and approved by a resolution of each House of Parliament, and the Secretary of State may not lay a draft before Parliament except after consultation with or on the recommendation of the Advisory Council: *ibid* s 2(5). Any such order may amend Sch 2 Pt IV (definitions), whether or not it amends any other Part (s 2(3)); and may be varied or revoked by a subsequent order (s 2(4)). For the meaning of 'the Advisory Council' see PARA 246 note 1 post. As to the Secretary of State see PARA 3 note 3 ante. As to the laying of documents before Parliament see PARLIAMENT vol 34 (Reissue) PARA 941.

7 Such amendments may include amendments for securing that no substance or product is for the time being specified in a particular Part or for inserting one into any of those Parts in which no substance or product is for the time being specified: *ibid* s 2(2).

8 *Ibid* s 2(2). The following orders have been made: the Misuse of Drugs Act 1971 (Modification) Order 1973, SI 1973/771; the Misuse of Drugs Act 1971 (Modification) Order 1975, SI 1975/421; the Misuse of Drugs Act 1971 (Modification) Order 1977, SI 1977/1243; the Misuse of Drugs Act 1971 (Modification) Order 1979, SI 1979/299; the Misuse of Drugs Act 1971 (Modification) Order 1983, SI 1983/765; the Misuse of Drugs Act 1971 (Modification) Order 1984, SI 1984/859; the Misuse of Drugs Act 1971 (Modification) Order 1985, SI 1985/1995; the Misuse of Drugs Act 1971 (Modification) Order 1986, SI 1986/2230 (amended by SI 1995/1966); the Misuse of Drugs Act 1971 (Modification) Order 1989, SI 1989/1340; the Misuse of Drugs Act 1971 (Modification) Order 1990, SI 1990/2589; the Misuse of Drugs Act 1971 (Modification) Order 1995, SI 1995/1966; the Misuse of Drugs Act 1971 (Modification) Order 1996, SI 1996/1300; the Misuse of Drugs Act 1971 (Modification) Order 1998, SI 1998/750; the Misuse of Drugs Act 1971 (Modification) Order 2001, SI 2001/3932; the Misuse of Drugs Act 1971 (Modification) Order 2003, SI 2003/1243; and the Misuse of Drugs Act 1971 (Modification) (No 2) Order 2003, SI 2003/3201.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

238 Controlled drugs

NOTE 8--SI 2003/3201 replaced: SI 2008/3130. See also the Misuse of Drugs Act 1971 (Amendment) Order 2005, SI 2005/3178.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(1) INTRODUCTION/239. Class A drugs.

239. Class A drugs.

The controlled drugs¹ which are Class A drugs² are:

- 209 (1) the following substances and products:
27
 33. (a) acetorphine;
 34. alfentanil;
 35. allylprodine;
 36. alphacetylmethadol;
 37. alphameprodine;
 38. alphamethadol;
 39. alphaprodine;
 40. anileridine;
 41. benzethidine;
 42. benzylmorphine (3-benzylmorphine);
 43. betacetylmethadol;
 44. betameprodine;
 45. betamethadol;
 46. betaprodine;
 47. bezitramide;
 48. bufotenine;
 49. carfentanil;
 50. clonitazene;
 51. coca leaf³;
 52. cocaine⁴;
 53. desomorphine;
 54. dextromoramide;
 55. diamorphine;
 56. diampromide;
 57. diethylthiambutene;
 58. difenoxin (1-(3-cyano-3,3-diphenylpropyl)-4-phenylpiperidine-4-carboxylic acid);
 59. dihydrocodeinone *O*-carboxymethyloxime;
 60. dihydroetorphine;
 61. dihydromorphine;
 62. dimenoxadole;
 63. dimepheptanol;
 64. dimethylthiambutene;
 65. dioxaphetyl butyrate;
 66. diphenoxylate;
 67. dipipanone;
 68. drotebanol (3, 4-dimethoxy-17-methylmorphinan-6 β ,14-diol);
 69. ecgonine and any derivative thereof which is convertible to ecgonine or to cocaine;
 70. ethylmethylthiambutene;
 71. eticyclidine;
 72. etonitazene;
 73. etorphine;
 74. etoxeridine;

75. tryptamine;
76. fentanyl;
77. fungus (of any kind) which contains psilocin or an ester of psilocin;
78. furethidine;
79. hydrocodone;
80. hydromorphenol;
81. hydromorphone;
82. hydroxypethidine;
83. *N*-hydroxy-tenamphetamine;
84. isomethadone;
85. ketobemidone;
86. levomethorphan;
87. levomoramide;
88. levophenacylmorphan;
89. levorphanol;
90. lofentanil;
91. lysergamide;
92. lysergide and other *N*-alkyl derivatives of lysergamide;
93. mescaline;
94. metazocine;
95. methadone;
96. methadyl acetate;
97. methyl-desorphine;
98. methyldihydromorphine (6-methyldihydromorphine);
99. metopon;
100. morpheridine;
101. morphine;
102. morphine methobromide, morphine *N*-oxide and other pentavalent nitrogen morphine derivatives;
103. myrophine;
104. nicomorphine (3,6-dinicotinoyl-morphine);
105. noracymethadol;
106. norlevorphanol;
107. normethadone;
108. normorphine;
109. norpipanone;
110. opium, whether raw⁵, prepared or medicinal⁶;
111. oxycodone;
112. oxymorphone;
113. pethidine;
114. phenadoxone;
115. phenampromide;
116. phenazocine;
117. phencyclidine;
118. phenomorphan;
119. phenoperidine;
120. piminodine;
121. piritramide;
122. poppy-straw⁷ and concentrate of poppy-straw⁸;
123. proheptazine;
124. properidine (1-methyl-4-phenyl-piperidine-4-carboxylic acid isopropyl ester);
125. psilocin;
126. racemethorphan;
127. racemoramide;
128. racemorphan;

129. remifentanil;
130. rolicyclidine;
131. sufentanil;
132. tenocyclidine;
133. thebacon;
134. thebaine;
135. tilidate;
136. trimeperidine;
137. 4-bromo-2,5-dimethoxy-*a*-methylphenethylamine;
138. 4-cyano-2-dimethylamino-4,4-diphenylbutane;
139. 4-cyano-1-methyl-phenyl-piperidine;
140. *N,N*-diethyltryptamine;
141. *N,N*-dimethyltryptamine;
142. 2,5-dimethoxy-*a*-4-dimethylphenethylamine;
143. *N*-hydroxy-tenamphetamine;
144. 1-methyl-4-phenyl-piperidine-4-carboxylic acid;
145. 2-methyl-3-morpholino-1,1-diphenyl-propanecarboxylic acid;
146. 4-methyl-aminorex;
147. 4-phenylpiperidine-4-carboxylic acid ethyl ester⁹;
148. (b) any compound (not being a compound for the time being specified in head (1)(a) above) structurally derived from¹⁰ tryptamine or from a ring-hydroxy tryptamine by substitution at the nitrogen atom of the sidechain with one or more alkyl substituents but no other substituent¹¹;
149. (c) the following phenethylamine derivatives:
 150. allyl(*a*-methyl-3,4-methylenedioxyphenethyl)amine;
 151. 2-amino-1-(2,5-dimethoxy-4-methylphenyl)ethanol;
 152. 2-amino-1-(3,4-dimethoxyphenyl)ethanol;
 153. benzyl(*a*-methyl-3,4-methylenedioxyphenethyl)amine;
 154. 4-bromo-*b*,2,5-trimethoxyphenethylamine;
 155. *N*-(4-*sec*-butylthio-2,5-dimethoxyphenethyl)hydroxylamine;
 156. cyclopropylmethyl(*a*-methyl-3,4-methylenedioxyphenethyl)amine;
 157. 2-(4,7-dimethoxy-2,3-dihydro-1*H*-indan-5-yl)ethylamine;
 158. 2-(4,7-dimethoxy-2,3-dihydro-1*H*-indan-5-yl)-1-methylethylamine;
 159. 2-(2,5-dimethoxy-4-methylphenyl)cyclopropylamine;
 160. 2-(1,4-dimethoxy-2-naphthyl)ethylamine;
 161. 2-(1,4-dimethoxy-2-naphthyl)-1-methylethylamine;
 162. *N*-(2,5-dimethoxy-4-propylthiophenethyl)hydroxylamine;
 163. 2-(1,4-dimethoxy-5,6,7,8-tetrahydro-2-naphthyl)ethylamine;
 164. 2-(1,4-dimethoxy-5,6,7,8-tetrahydro-2-naphthyl)-1-methylethylamine;
 165. *a,a*-dimethyl-3,4-methylenedioxyphenethylamine;
 166. *a,a*-dimethyl-3,4-methylenedioxyphenethyl(methyl)amine;
 167. dimethyl(*a*-methyl-3,4-methylenedioxyphenethyl)amine;
 168. *N*-(4-ethylthio-2,5-dimethoxyphenethyl)hydroxylamine;
 169. 4-iodo-2,5-dimethoxy-*a*-methylphenethyl(dimethyl)amine;
 170. 2-(1,4-methano-5,8-dimethoxy-1,2,3,4-tetrahydro-6-naphthyl)ethylamine;
 171. 2-(1,4-methano-5,8-dimethoxy-1,2,3,4-tetrahydro-6-naphthyl)-1-methylethylamine;
 172. 2-(5-methoxy-2,2-dimethyl-2,3-dihydrobenzo[*b*]furan-6-yl)-1-methylethylamine;
 173. 2-methoxyethyl(*a*-methyl-3,4-methylenedioxyphenethyl)amine;
 174. 2-(5-methoxy-2-methyl-2,3-dihydrobenzo[*b*]furan-6-yl)-1-methylethylamine;
 175. *b*-methoxy-3,4-methylenedioxyphenethylamine;
 176. 1-(3,4-methylenedioxybenzyl)butyl(ethyl)amine;
 177. 1-(3,4-methylenedioxybenzyl)butyl(methyl)amine;
 178. 2-(*a*-methyl-3,4-methylenedioxyphenethylamino)ethanol;

- 179. *a*-methyl-3,4-methylenedioxyphenethyl(prop-2-ynyl)amine;
 - 180. *N*-methyl-*N*-(*a*-methyl-3,4-methylenedioxyphenethyl)hydroxylamine;
 - 181. *O*-methyl-*N*-(*a*-methyl-3,4-methylenedioxyphenethyl)hydroxylamine;
 - 182. *a*-methyl-4-(methylthio)phenethylamine;
 - 183. *b*,3,4,5-tetramethoxyphenethylamine;
 - 184. *b*,2,5-trimethoxy-4-methylphenethylamine¹²;
 - 185. (d) any compound (not being methoxyphenamine or a compound for the time being specified in head (1)(a) above) structurally derived from: phenethylamine,
 - 186. an *N*-alkylphenethylamine,
 - 187. *a*-methylphenethylamine,
 - 188. an *N*-alkyl-*a*-methylphenethylamine,
 - 189. *a*-ethylphenethylamine, or
 - 190. *N*-alkyl-*a*-ethylphenethylamine,
 - 191. by substitution in the ring to any extent with alkyl, alkoxy, alkylenedioxy or halide substituents, whether or not further substituted in the ring by one or more other univalent substituents¹³;
 - 192. (e) any compound (not being a compound for the time being specified in head (1)(a) above) structurally derived from fentanyl by modification in any of the following ways: (i) replacement of the phenyl portion of the phenethyl group by any heteromonocycle whether or not further substituted in the heterocycle; (ii) substitution in the phenethyl group with alkyl, alkenyl, alkoxy, hydroxy, halogeno, haloalkyl, amino or nitro groups; (iii) substitution in the piperidine ring with alkyl or alkenyl groups; (iv) substitution in the aniline ring with alkyl, alkoxy, alkylenedioxy, halogeno or haloalkyl groups; (v) substitution at the 4-position of the piperidine ring with any alkoxycarbonyl or alkoxyalkyl or acyloxy group; (vi) replacement of the *N*-propionyl group by another acyl group¹⁴;
 - 193. (f) any compound (not being a compound for the time being specified in head (1)(a) above) structurally derived from pethidine by modification in any of the following ways: (i) replacement of the 1-methyl group of an acyl, alkyl whether or not unsaturated, benzyl or phenethyl group, whether or not further substituted; (ii) substitution in the piperidine ring with alkyl or alkenyl groups or with a propano bridge, whether or not further substituted; (iii) substitution in the 4-phenyl ring with alkyl, alkoxy, aryloxy, halogeno or haloalkyl groups; (iv) replacement of the 4-ethoxycarbonyl by any other alkoxycarbonyl or any alkoxyalkyl or acyloxy group; (v) formation of an *N*-oxide or of a quaternary base¹⁵;
- 28
- 210 (2) any stereoisomeric form of a substance for the time being specified in head (1) above, not being dextromethorphan or dextrorphan¹⁶;
 - 211 (3) any ester or ether of a substance for the time being specified in head (1) or head (2) above, not being a substance for the time being specified as a Class B drug¹⁷;
 - 212 (4) any salt of a substance for the time being specified in any of heads (1) to (3) above¹⁸;
 - 213 (5) any preparation or other product containing a substance or product for the time being specified in any of heads (1) to (4) above¹⁹;
 - 214 (6) any preparation designed for administration by injection which includes any of certain substances or products²⁰ for the time being specified as Class B drugs²¹.

Since 'heroin' is not listed as such, an indictment in respect of heroin should refer to 'diamorphine (commonly known as 'heroin')'²².

1 For the meaning of 'controlled drug' see PARA 238 ante.

2 For the meaning of 'Class A drug' see PARA 238 ante. As to the power to make orders amending the list of controlled drugs see the Misuse of Drugs Act 1971 s 2(2)-(5); and PARA 238 ante.

3 'Coca leaf' means the leaf of any plant of the genus *Erythroxylon* from whose leaves cocaine can be extracted either directly or by chemical transformation: Misuse of Drugs Act 1971 Sch 2 Pt IV.

4 To establish possession of cocaine, it is sufficient to prove that the substance is either cocaine or a stereoisomeric form or a salt within ibid Sch 2 Pt 1 paras 2-5: see *R v Greensmith* [1983] 3 All ER 444, [1983] 1 WLR 1124, CA. The conversion of cocaine hydrochloride, a substance falling within the Misuse of Drugs Act 1971 Sch 2 Pt I para 4, into free base cocaine, a substance falling within Sch 2 Pt I para 1, may however amount to 'production' of a controlled drug by means other than manufacture or cultivation: *R v Russell* (1991) 94 Cr App Rep 351, CA; and see the Misuse of Drugs Act 1971 ss 4(2), 37(1), Sch 2 Pt I.

5 'Raw opium' includes powdered or granulated opium but does not include medicinal opium: ibid Sch 2 Pt IV.

6 'Medicinal opium' means raw opium (see note 5 supra) which has undergone the process necessary to adapt it for medicinal use in accordance with the requirements of the British Pharmacopoeia (see PARA 149 et seq ante), whether it is in the form of powder or is granulated or is in any other form, and whether it is or is not mixed with neutral substances: ibid Sch 2 Pt IV.

7 'Poppy-straw' means all parts, except the seeds, of the opium poppy after mowing, and 'opium poppy' means the plant of the species *Papaver somniferum* L: ibid Sch 2 Pt IV.

8 'Concentrate of poppy-straw' means the material produced when poppy-straw (see note 7 supra) has entered into a process for the concentration of its alkaloids: ibid Sch 2 Pt IV.

9 Ibid Sch 2 Pt I para 1(a) (so designated by the Misuse of Drugs Act 1971 (Modification) Order 1977, SI 1977/1243; and amended by the Misuse of Drugs Act 1971 (Modification) Order 1973, SI 1973/771; the Misuse of Drugs Act 1971 (Modification) Order 1975, SI 1975/421; the Misuse of Drugs Act 1971 (Modification) Order 1979, SI 1979/299; the Misuse of Drugs Act 1971 (Modification) Order 1983, SI 1983/765; the Misuse of Drugs Act 1971 (Modification) Order 1984, SI 1984/859; the Misuse of Drugs Act 1971 (Modification) Order 1986, SI 1986/2230; the Misuse of Drugs Act 1971 (Modification) Order 1990, SI 1990/2589; the Misuse of Drugs Act 1971 (Modification) Order 1998, SI 1998/750; the Misuse of Drugs Act 1971 (Modification) Order 2003, SI 2003/1243; the Misuse of Drugs Act 1971 (Modification) (No 2) Order 2003, SI 2003/3201; and the Drugs Act 2005 s 21).

10 As to the interpretation of 'structurally derived from' see *R v Couzens and Frankel* (1992) 14 Cr App Rep (S) 33, [1992] Crim LR 822, CA.

11 Misuse of Drugs Act 1971 Sch 2 Pt I para 1(b) (added by the Misuse of Drugs Act 1971 (Modification) Order 1977, SI 1977/1243).

12 Misuse of Drugs Act 1971 Sch 2 Pt I para 1(ba) (added by the Misuse of Drugs Act 1971 (Modification) Order 2001, SI 2001/3932).

13 Misuse of Drugs Act 1971 Sch 2 Pt I para 1(c) (added by the Misuse of Drugs Act 1971 (Modification) Order 1977, SI 1977/1243). See also note 10 supra.

14 Misuse of Drugs Act 1971 Sch 2 Pt I para 1(d) (added by the Misuse of Drugs Act 1971 (Modification) Order 1986, SI 1986/2230). See also note 10 supra.

15 Misuse of Drugs Act 1971 Sch 2 Pt I para 1(e) (added by the Misuse of Drugs Act 1971 (Modification) Order 1986, SI 1986/2230). See also note 10 supra.

16 Misuse of Drugs Act 1971 Sch 2 Pt I para 2.

17 Ibid Sch 2 Pt I para 3 (amended by the Misuse of Drugs Act 1971 (Modification) Order 1973, SI 1973/771). For the meaning of 'Class B drug' see PARA 238 ante; and as to such drugs see PARA 240 post.

18 Misuse of Drugs Act 1971 Sch 2 Pt I para 4.

19 Ibid Sch 2 Pt I para 5. 'Preparation' should be given its ordinary and natural meaning: *R v Stevens* [1981] Crim LR 568, CA (psilocybin-containing mushrooms were prepared by merely ceasing to be in their natural growing state and being in some way altered by the hand of man to make them into a condition in which they could be used). In *R v Cunliffe* [1986] Crim LR 547, CA, it was held that it was open to the jury to find that the defendants' picking a quantity of mushrooms and subjecting them to a drying process involved an act of preparation for future use. See also *R v Walker* [1987] Crim LR 565, CA. In *Hodder v DPP*, *Matthews v DPP*

[1990] Crim LR 261, CA, it was held that picking, packaging and freezing mushrooms did not constitute 'preparation', although the mushrooms did constitute a 'product'.

20 le any substance or product for the time being specified in the Misuse of Drugs Act 1971 Sch 2 Pt II paras 1-3: see PARA 240 post.

21 Ibid Sch 2 Pt I para 6. See also note 19 supra.

22 See *R v Macauley* (1967) 111 Sol Jo 791, CA.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

239 Class A drugs

TEXT AND NOTE 9--Head 1(a), after 'methadyl acetate' add 'methamphetamine': Misuse of Drugs Act 1971 Sch 2 Pt I para 1(a) (amended by SI 2006/3331).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(1) INTRODUCTION/240. Class B drugs.

240. Class B drugs.

The controlled drugs¹ which are Class B drugs² are:

- 215 (1) the following substances and products:
29
- 194. (a) acetyldihydrocodeine;
 - 195. amphetamine³;
 - 196. codeine;
 - 197. dihydrocodeine;
 - 198. ethylmorphine (3-ethylmorphine);
 - 199. glutethimide;
 - 200. lefetamine;
 - 201. mecloqualone;
 - 202. methaqualone;
 - 203. methcathinone;
 - 204. methylamphetamine;
 - 205. *a*-methylphenethylhydroxylamine;
 - 206. methylphenidate;
 - 207. methylphenobarbitone;
 - 208. nicocodine;
 - 209. nicodicodine (6-nicotinoyldihydrocodeine);
 - 210. norcodeine;
 - 211. pentazocine;
 - 212. phenmetrazine;
 - 213. pholcodine;
 - 214. propiram;
 - 215. zipeprol⁴;
 - 216. (b) any 5,5 disubstituted barbituric acid⁵;
- 30
- 216 (2) any stereoisomeric form of a substance for the time being specified in head (1) above⁶;
- 217 (3) any salt of a substance for the time being specified in head (1) or head (2) above⁷;
- 218 (4) any preparation or other product containing a substance or product for the time being specified in any of heads (1) to (3) above, not being any of certain preparations⁸ specified as Class A drugs⁹.

1 For the meaning of 'controlled drug' see PARA 238 ante.

2 For the meaning of 'Class B drug' see PARA 238 ante. As to the power to make orders amending the list of controlled drugs see the Misuse of Drugs Act 1971 s 2(2)-(5); and PARA 238 ante.

3 The word 'amphetamine' is generic and embraces all of its stereoisomers; accordingly, pure dexamphetamine and pure levoamphetamine are both 'amphetamine' for the purposes of the Act: *R v Watts* [1984] 2 All ER 380, [1984] 1 WLR 757, CA.

4 Misuse of Drugs Act 1971 s 2(1), Sch 2 Pt II para 1(a) (so designated by the Misuse of Drugs Act 1971 (Modification) Order 1984, SI 1984/859; and amended by the Misuse of Drugs Act 1971 (Modification) Order 1973, SI 1973/771; the Misuse of Drugs Act 1971 (Modification) Order 1984, SI 1984/859; the Misuse of Drugs Act 1971 (Modification) Order 1985, SI 1985/1995; the Misuse of Drugs Act 1971 (Modification) Order 1998, SI

1998/750; the Misuse of Drugs Act 1971 (Modification) Order 2001, SI 2001/3932; and the Misuse of Drugs Act 1971 (Modification) (No 2) Order 2003, SI 2003/3201).

5 Misuse of Drugs Act 1971 Sch 2 Pt II para 1(b) (added by the Misuse of Drugs Act 1971 (Modification) Order 1984, SI 1984/859).

6 Misuse of Drugs Act 1971 Sch 2 Pt II para 2. See *R v Watts* [1984] 2 All ER 380, [1984] 1 WLR 757, CA; and note 3 *supra*.

7 Misuse of Drugs Act 1971 Sch 2 Pt II para 3.

8 I.e. a preparation falling within *ibid* Sch 2 Pt I para 6: see PARA 239 *ante*.

9 *Ibid* Sch 2 Pt II para 4. For the meaning of 'Class A drug' see PARA 238 *ante*.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

240 Class B drugs

TEXT AND NOTE 4--Head 1(a) omit 'methamphetamine'; add 'cannabinol', 'cannabinol derivatives', 'cannabis and cannabis resin': Misuse of Drugs Act 1971 Sch 2 Pt II para 1(a) (amended by SI 2006/3331; SI 2008/3130).

NOTE 5--Misuse of Drugs Act 1971 Sch 2 Pt II para 1(c) added: SI 2009/3209.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3.
CONTROLLED DRUGS/(1) INTRODUCTION/241. Class C drugs.

241. Class C drugs.

The controlled drugs¹ which are Class C drugs² are:

219 (1) the following substances:

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- 217. (a) alprazolam;
- 218. aminorex;
- 219. benzphetamine;
- 220. bromazepam;
- 221. brotizolam;
- 222. buprenorphine;
- 223. camazepam;
- 224. cannabinal;
- 225. cannabinal derivatives³;
- 226. cannabis⁴ and cannabis resin⁵;
- 227. cathine;
- 228. cathinone;
- 229. chlordiazepoxide;
- 230. chlorphentermine;
- 231. clobazam;
- 232. clonazepam;
- 233. clorazepic acid;
- 234. clotiazepam;
- 235. cloxazolam;
- 236. delorazepam;
- 237. dextropropoxyphene;
- 238. diazepam;
- 239. diethylpropion;
- 240. estazolam;
- 241. ethchlorvynol;
- 242. ethinamate;
- 243. ethyl loflazepate;
- 244. fencamfamin;
- 245. fenethylline;
- 246. fenproporex;
- 247. fludiazepam;
- 248. flunitrazepam;
- 249. flurazepam;
- 250. halazepam;
- 251. haloxazolam;
- 252. 4-hydroxy-n-butyric acid;
- 253. ketazolam;
- 254. lorazepam;
- 255. lorazepam;
- 256. lormetazepam;
- 257. mazindol;
- 258. medazepam;
- 259. mefenorex;

- 260. mephentermine;
- 261. meprobamate;
- 262. mesocarb;
- 263. methypylone;
- 264. midazolam;
- 265. nimetazepam;
- 266. nitrazepam;
- 267. nordazepam;
- 268. oxazepam;
- 269. oxazolam;
- 270. pemoline;
- 271. phendimetrazine;
- 272. phentermine;
- 273. pinazepam;
- 274. pipradrol;
- 275. prazepam;
- 276. pyrovalerone;
- 277. temazepam;
- 278. tetrazepam;
- 279. triazolam;
- 280. *N*-ethylamphetamine;
- 281. zolpidem⁶;
- 282. (b) 4-androstene-3, 17-dione;
- 283. 5-androstene-3, 17-diol;
- 284. atamestane; bolandiol;
- 285. bolasterone;
- 286. bolazine;
- 287. boldenone;
- 288. bolenol;
- 289. bolmantalate;
- 290. calusterone;
- 291. 4-chloromethandienone;
- 292. clostebol;
- 293. drostanolone;
- 294. enestebol;
- 295. epitiostanol;
- 296. ethyloestrenol;
- 297. fluoxymesterone;
- 298. formebolone;
- 299. furazabol;
- 300. mebolazine;
- 301. mepitiothane;
- 302. mesabolone;
- 303. mestanolone;
- 304. mesterolone;
- 305. methandienone;
- 306. methandriol;
- 307. methenolone;
- 308. methyltestosterone;
- 309. metribolone;
- 310. mibolerone;
- 311. nandrolone;
- 312. 19-nor-4-androstene-3, 17-dione;
- 313. 19-nor-5-androstene-3, 17-diol;
- 314. norboletone;

- 315. norclostebol;
 - 316. norethandrolone;
 - 317. ovandrotone;
 - 318. oxabolone;
 - 319. oxandrolone;
 - 320. oxymesterone;
 - 321. oxymetholone;
 - 322. prasterone;
 - 323. propetandrol;
 - 324. quinbolone;
 - 325. roxibolone;
 - 326. silandrone;
 - 327. stanolone;
 - 328. stanozolol;
 - 329. stenbolone;
 - 330. testosterone;
 - 331. thiomesterone;
 - 332. trenbolone⁷;
 - 333. (c) any compound (not being trilostane or a compound for the time being specified in head (1)(b) above) structurally derived from 17-hydroxyandrostan-3-one or from 17-hydroxyestrane-3-one by modification in any of the following ways, that is to say: (i) by further substitution at position 17 by a methyl or ethyl group; (ii) by substitution to any extent at one or more of positions 1, 2, 4, 6, 7, 9, 11 or 16, but at no other position; (iii) by unsaturation in the carbocyclic ring system to any extent, provided that there are no more than two ethylenic bonds in any one carbocyclic ring; (iv) by fusion of ring A with a heterocyclic system⁸;
 - 334. (d) any substance which is an ester or ether (or, where more than one hydroxyl function is available, both an ester and an ether) of a substance specified in head (1)(b) or described in head (1)(c) above or of cannabinol or a cannabinol derivative⁹;
 - 335. (e) chorionic gonadotrophin (HCG); clenbuterol; non-human chorionic gonadotrophin; somatotropin; somatrem; somatotropin¹⁰;
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- 220 (2) any stereoisomeric form of a substance for the time being specified in head (1) above not being phenylpropanolamine¹¹;
 - 221 (3) any salt of a substance for the time being specified in head (1) or head (2) above¹²;
 - 222 (4) any preparation or other product containing a substance for the time being specified in any of heads (1) to (3) above¹³.

1 For the meaning of 'controlled drug' see PARA 238 ante.

2 For the meaning of 'Class C drug' see PARA 238 ante. As to the power to make orders amending the list of controlled drugs see the Misuse of Drugs Act 1971 s 2(2)-(5); and PARA 238 ante.

3 'Cannabinol derivatives' means the following substances (except where contained in cannabis or cannabis resin: see notes 4-5 infra): tetrahydro derivatives of cannabinol and 3-alkyl homologues of cannabinol or of its tetrahydro derivatives: Misuse of Drugs Act 1971 s 2(1), Sch 2 Pt IV. Possession of a cannabinol derivative is not established by proof of possession of naturally occurring material, namely the leaf and stalk of the plant *Cannabis sativa*, of which a cannabinol derivative is an unseparated constituent: *DPP v Goodchild* [1978] 2 All ER 161, [1978] 1 WLR 578, HL (reversing in this regard [1978] 1 All ER 649, [1977] 1 WLR 1213, CA (Criminal Division)).

4 'Cannabis' (except in the expression 'cannabis resin': see note 5 infra) means any plant of the genus *Cannabis* or any part of any such plant (by whatever name designated) except that it does not include cannabis resin or any of the following products after separation from the rest of the plant, namely, mature stalk of any such plant, fibre produced from such mature stalk, and seed of any such plant: Misuse of Drugs Act 1971 s

37(1) (definition substituted by the Criminal Law Act 1977 s 52). The substitution of this definition followed the decisions in *R v Goodchild* [1977] 2 All ER 163, [1977] 1 WLR 473, CA, and *R v Mitchell* [1977] 2 All ER 168, [1977] 1 WLR 753, CA, to the effect that the original definition did not include the leaves and stalk or cleaned seeds. See also note 3 supra.

5 'Cannabis resin' means the separated resin, whether crude or purified, obtained from any plant of the genus *Cannabis*: Misuse of Drugs Act 1971 s 37(1). The mere possession of leaves and stalk of a cannabis plant which contain resin does not amount to the unlawful possession of cannabis resin. To constitute 'separated resin', there has to be a deliberate removal by some process of the resin of the plant: *R v Goodchild (No 2)*, *A-G's Reference (No 1 of 1977)* [1978] 1 All ER 649, [1977] 1 WLR 1213, CA; affd sub nom *DPP v Goodchild* [1978] 2 All ER 161, [1978] 1 WLR 578, HL. See also note 3 supra.

6 Misuse of Drugs Act 1971 Sch 2 Pt III para 1(a) (so designated by the Misuse of Drugs Act 1971 (Modification) Order 1996, SI 1996/1300; and amended by the Misuse of Drugs Act 1971 (Modification) Order 1973, SI 1973/771; the Misuse of Drugs Act 1971 (Modification) Order 1983, SI 1983/765; the Misuse of Drugs Act 1971 (Modification) Order 1984, SI 1984/859; the Misuse of Drugs Act 1971 (Modification) Order 1985, SI 1985/1995; the Misuse of Drugs Act 1971 (Modification) Order 1986, SI 1986/2230; the Misuse of Drugs Act 1971 (Modification) Order 1989, SI 1989/1340; the Misuse of Drugs Act 1971 (Modification) Order 1990, SI 1990/2589; the Misuse of Drugs Act 1971 (Modification) Order 1995, SI 1995/1966; the Misuse of Drugs Act 1971 (Modification) Order 1998, SI 1998/750; the Misuse of Drugs Act 1971 (Modification) Order 2003, SI 2003/1243; and the Misuse of Drugs Act 1971 (Modification) (No 2) Order 2003, SI 2003/3201).

7 Misuse of Drugs Act 1971 Sch 2 Pt III para 1(b) (Sch 2 Pt III para 1(b)-(e) added by the Misuse of Drugs Act 1971 (Modification) Order 1996, SI 1996/1300; and the Misuse of Drugs Act 1971 Sch 2 Pt III para 1(b) amended by the Misuse of Drugs Act 1971 (Modification) Order 2003, SI 2003/1243).

8 Misuse of Drugs Act 1971 Sch 2 Pt III para 1(c) (as added: see note 7 supra).

9 Ibid Sch 2 Pt III para 1(d) (as added (see note 7 supra); and amended by the Misuse of Drugs Act 1971 (Modification) (No 2) Order 2003, SI 2003/3201).

10 Misuse of Drugs Act 1971 Sch 2 Pt III para 1(e) (as added: see note 7 supra).

11 Ibid Sch 2 Pt III para 2 (amended by the Misuse of Drugs Act 1971 (Modification) Order 1986, SI 1986/2230).

12 Misuse of Drugs Act 1971 Sch 2 Pt III para 3.

13 Ibid Sch 2 Pt III para 4.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

241 Class C drugs

TEXT AND NOTE 6--Head 1(a) add 'ketamine'; omit 'cannabinol', 'cannabinol derivatives', 'cannabis and cannabis resin'; add 'gamma-butyrolactone': Misuse of Drugs Act 1971 Sch 2 Pt III para 1(a) (amended by SI 2005/3178; SI 2008/3130, SI 2009/3209).

TEXT AND NOTE 7--Head 1(b) add '5a-androstane-3, 17-diol', 'androst-4-ene-3, 17-diol', '1-androstenediol', '1-androstenedione', '5-androstenedione', 'boldione', '1, 4-bbutanediol', 'danazol', 'desoxymethyltestosterone', 'gestrinone', '3-hydroxy-5a-androstan-17-one', 'norandrostenedione', '19-norandrosterone', '19-noretiocholanolone', 'oripavine', 'prostanazol', 'tetrahydrogestrinone': Misuse of Drugs Act 1971 Sch 2 Pt III para 1(b) (amended by SI 2009/3209).

NOTE 8--Misuse of Drugs Act 1971 Sch 2 Pt III para 1(ca) added: SI 2009/3209.

NOTE 10--Head 1(e) add 'zeranol' and 'zilpaterol': Misuse of Drugs Act 1971 Sch 2 Pt III para 1(e) (amended by SI 2009/3209).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(1) INTRODUCTION/242. Regulations generally.

242. Regulations generally.

Regulations made by the Secretary of State¹ under any provision of the Misuse of Drugs Act 1971 may: (1) make different provision in relation to different controlled drugs², different classes of persons³, different provisions of the Act or other different cases or circumstances⁴; (2) make the opinion, consent or approval of a prescribed⁵ authority or of any person authorised in a prescribed manner material for purposes of any provision of the regulations⁶; and (3) contain such supplementary, incidental and transitional provisions as appear expedient to the Secretary of State⁷.

Any power of the Secretary of State to make regulations under the Act is exercisable by statutory instrument, which is subject to annulment in pursuance of a resolution of either House of Parliament⁸. The Secretary of State may not make any regulations under the Act except after consultation with the Advisory Council⁹.

1 As to the Secretary of State see PARA 3 note 3 ante.

2 For the meaning of 'controlled drug' see PARA 238 ante.

3 For the meaning of 'person' see PARA 21 note 7 ante.

4 Misuse of Drugs Act 1971 s 31(1)(a).

5 'Prescribed' means prescribed by regulations made by the Secretary of State under the Misuse of Drugs Act 1971: s 37(1).

6 Ibid s 31(1)(b).

7 Ibid s 31(1)(c).

8 Ibid s 31(2). As from a day to be appointed, this provision has effect subject to s 31(2A) (prospectively added), which provides that a statutory instrument containing regulations under s 5(4A) (prospectively added) (see PARA 252 post) must not be made unless a draft of the instrument has been laid before, and approved by a resolution of, each House of Parliament: s 31(2), (2A) (s 31(2) prospectively amended, and s 31(2A) prospectively added, by the Drugs Act 2005 ss 2(1), (3), 24(3)). At the date at which this volume states the law, no such day had been appointed. As to the annulment of statutory instruments see STATUTES vol 44(1) (Reissue) PARA 1516. As to the laying of documents before Parliament see PARLIAMENT vol 34 (Reissue) PARA 941.

9 Misuse of Drugs Act 1971 s 31(3). For the meaning of 'the Advisory Council' see PARA 246 note 1 post.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(1) INTRODUCTION/243. Variation of the Misuse of Drugs Act 1971 by regulation.

243. Variation of the Misuse of Drugs Act 1971 by regulation.

The Secretary of State¹ may by regulations² make provision for:

- 223 (1) excluding in such cases as may be prescribed³ the application of any provision of the Misuse of Drugs Act 1971 which creates an offence⁴ or the application of any of certain provisions of the Customs and Excise Management Act 1979⁵ in so far as they apply in relation to a prohibition or restriction on importation or exportation of a controlled drug⁶;
- 224 (2) applying any of the provisions of the Misuse of Drugs Act 1971⁷ relating to investigation of cases by tribunals, advisory bodies or professional panels, with such modifications, if any, as may be prescribed, in relation to any proposal by the Secretary of State to give a direction⁸ prohibiting a practitioner⁹ or pharmacist¹⁰ convicted of the specified offences from being concerned with controlled drugs¹¹, or for such purposes of regulations under the Act as may be prescribed¹²; and
- 225 (3) the application of any of the provisions of the Act or regulations or orders made under it to servants or agents of the Crown, subject to such exceptions, adaptations and modifications as may be prescribed¹³.

1 As to the Secretary of State see PARA 3 note 3 ante.

2 As to the making of regulations see PARA 242 ante. As to regulations made under this provision see the Misuse of Drugs Regulations 2001, SI 2001/3998 (amended by SI 2003/1432; SI 2003/1653; SI 2003/2429; SI 2004/1031; SI 2004/1771; SI 2005/271); and the Misuse of Drugs (Supply to Addicts) Regulations 1997, SI 1997/1001.

3 For the meaning of 'prescribed' see PARA 242 note 5 ante.

4 Misuse of Drugs Act 1971 s 22(a)(i).

5 Ie the Customs and Excise Management Act 1979 ss 50(1)-(4), 68(2), (3), 170: see PARA 248 note 2 post.

6 Misuse of Drugs Act 1971 s 22(a)(ii) (amended by the Customs and Excise Management Act 1979 s 177(1), Sch 4 para 12 Table Pt I). For the meaning of 'controlled drug' see PARA 238 ante.

7 Ie the Misuse of Drugs Act 1971 ss 14-16, Sch 3: see PARA 274 et seq post.

8 Ie under ibid s 12(2): see PARA 272 post.

9 'Practitioner' means a doctor, dentist, veterinary practitioner or veterinary surgeon: ibid s 37(1). 'Doctor' means a registered medical practitioner within the meaning of the Interpretation Act 1978 Sch 1 (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 4): Misuse of Drugs Act 1971 s 37(1) (definition substituted by the Medical Act 1983 s 56(1), Sch 5 para 9). 'Dentist' means a person registered in the dentists register under the Dentists Act 1984 or entered in the list of visiting EEA practitioners under Sch 4: Misuse of Drugs Act 1971 s 37(1) (definition amended by the Dentists Act 1984 s 54(1), Sch 5 para 3; and the Dental Qualifications (Recognition) Regulations 1996, SI 1996/1496, reg 7(b)). As to the registration of dentists see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 417 et seq. 'Veterinary practitioner' means a person registered in the supplementary veterinary register kept under the Veterinary Surgeons Act 1966 s 8 (see ANIMALS vol 2 (2008) PARA 1134); and 'veterinary surgeon' means a person registered in the register of veterinary surgeons kept under s 2 (see ANIMALS vol 2 (2008) PARA 1133): Misuse of Drugs Act 1971 s 37(1).

10 For the meaning of 'pharmacist' see PARA 46 note 10 ante; definition applied by ibid s 37(1).

11 Ibid s 22(b)(i). For the specified offences see s 12(1); and PARA 272 post.

12 Ibid s 22(b)(ii).

13 Ibid s 22(c). See also PARA 237 note 12 ante.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

243 Variation of the Misuse of Drugs Act 1971 by regulation

NOTE 2--SI 1997/1001 amended: SI 2005/2864. SI 2001/3998 further amended: SI 2005/2864, SI 2005/3372, SI 2006/986, SI 2006/1450, SI 2006/2178, SI 2007/2154, SI 2009/3136.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(1) INTRODUCTION/244. Licences and authorities generally.

244. Licences and authorities generally.

A licence or other authority issued by the Secretary of State¹ for purposes of the Misuse of Drugs Act 1971² or of regulations³ made under the Act may be issued, to any general or specific degree, on such terms and subject to such conditions including, in the case of a licence, the payment of a prescribed⁴ fee, as the Secretary of State thinks proper, and may be modified or revoked by him at any time⁵.

1 As to the Secretary of State see PARA 3 note 3 ante.

2 As to licences and authorities see the Misuse of Drugs Act 1971 s 3 (see PARA 248 post) and s 7 (see PARA 259 post).

3 As to the making of regulations see PARA 242 ante.

4 For the meaning of 'prescribed' see PARA 242 note 5 ante.

5 Misuse of Drugs Act 1971 s 30. As to the regulations that have been made see the Misuse of Drugs (Licence Fees) Regulations 1986, SI 1986/416 (amended by SI 2003/611).

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(1) INTRODUCTION/245. Service of notices and documents.

245. Service of notices and documents.

Any notice or other document required or authorised by any provision of the Misuse of Drugs Act 1971 to be served on any person¹ may be served on him either by delivering it to him or by leaving it at his proper address or by sending it by post². Any notice or other document so required or authorised to be served on a body corporate is duly served if it is served on the secretary or clerk of that body³. For these purposes⁴, the proper address of any person, in the case of the secretary or clerk of the body corporate, is that of the registered or principal office of that body and, in any other case, is the last address of the person to be served which is known to the Secretary of State⁵.

¹ For the meaning of 'person' see PARA 21 note 7 ante.

² Misuse of Drugs Act 1971 s 29(1). Where an Act authorises or requires any document to be served by post (whether the expression 'serve' or the expression 'give' or 'send' or any other expression is used) then, unless the contrary intention appears, the service is deemed to be effected by properly addressing, pre-paying and posting a letter containing the document and, unless the contrary is proved, to have been effected at the time at which the letter would be delivered in the ordinary course of post: Interpretation Act 1978 s 7. If a notice under the Misuse of Drugs Act 1971 s 11(1) (see PARA 265 post) or s 15(6) (see PARA 275 note 15 post) or, if a copy of a direction given under s 12(2), s 13(1) or (2) or s 16(3) (see PARAS 272-275 post) is served by sending it by registered post or by the recorded delivery service, service is deemed to have been effected at the time when the letter containing it would be delivered in the ordinary course of post; and so much of the Interpretation Act 1978 s 7 as relates to the time when service by post is deemed to have been effected does not apply to such a document if it is served by so sending it: see the Misuse of Drugs Act 1971 s 29(4).

³ Ibid s 29(2). As to bodies corporate see COMPANIES; CORPORATIONS.

⁴ Ie for the purposes of ibid s 29, and of the Interpretation Act 1978 s 7 (see note 2 supra) in its application to the Misuse of Drugs Act 1971 s 29.

⁵ Ibid s 29(3). As to the registered office of a company see COMPANIES vol 14 (2009) PARA 129.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(2) THE ADVISORY COUNCIL ON THE MISUSE OF DRUGS/246. The Advisory Council.

(2) THE ADVISORY COUNCIL ON THE MISUSE OF DRUGS

246. The Advisory Council.

An advisory body known as the Advisory Council on the Misuse of Drugs has been established¹. The members of the Advisory Council, of whom there must be not less than 20, are appointed by the Secretary of State² after consultation with such organisations as he considers appropriate³ and must include: (1) in relation to each of certain activities, at least one person appearing to the Secretary of State to have wide and recent experience of the activity⁴; and (2) persons with wide and recent experience of social problems connected with the misuse of drugs⁵. The activities mentioned above are: the practice of medicine, other than veterinary medicine⁶; the practice of dentistry⁷; the practice of veterinary medicine⁸; the practice of pharmacy⁹; the pharmaceutical industry¹⁰; and chemistry other than pharmaceutical chemistry¹¹. The Secretary of State must appoint one member of the Advisory Council to be chairman¹². The Secretary of State may pay to the members of the Advisory Council such remuneration, if any, and such travelling and other allowances as may be determined by him with the consent of the Treasury¹³; and any expenses incurred by the Advisory Council with the approval of the Secretary of State must be defrayed by him¹⁴.

The Advisory Council may appoint committees, which may consist in part of persons who are not members of the Advisory Council, to consider and report to it on any matters referred to them by the Advisory Council¹⁵. At meetings of the Advisory Council the quorum is seven, and subject to that it may determine its own procedure¹⁶.

1 Misuse of Drugs Act 1971 s 1(1). 'The Advisory Council' means the Advisory Council on the Misuse of Drugs so established: s 37(1). As to the duties of the Advisory Council see PARA 247 post.

2 As to the Secretary of State see PARA 3 note 3 ante.

3 Misuse of Drugs Act 1971 s 1(1), Sch 1 para 1(1).

4 Ibid Sch 1 para 1(1)(a).

5 Ibid Sch 1 para 1(1)(b). References to misusing a drug are references to misusing it by taking it; and the reference here to the taking of a drug is a reference to the taking of it by a human being by way of any form of self-administration, whether or not involving assistance by another: s 37(2).

6 Ibid Sch 1 para 1(2)(a).

7 Ibid Sch 1 para 1(2)(b).

8 Ibid Sch 1 para 1(2)(c).

9 Ibid Sch 1 para 1(2)(d).

10 Ibid Sch 1 para 1(2)(e).

11 Ibid Sch 1 para 1(2)(f).

12 Ibid Sch 1 para 1(3).

13 Ibid Sch 1 para 4 (amended by virtue of the Transfer of Functions (Minister for the Civil Service and Treasury) Order 1981, SI 1981/1670). As to the Treasury see CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARAS 512-517.

14 Misuse of Drugs Act 1971 Sch 1 para 5.

15 Ibid Sch 1 para 2.

16 Ibid Sch 1 para 3.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(2) THE ADVISORY COUNCIL ON THE MISUSE OF DRUGS/247. Duties of the Advisory Council.

247. Duties of the Advisory Council.

It is the duty of the Advisory Council¹ to keep under review the situation in the United Kingdom² with respect to drugs which are being or appear to it likely to be misused³ and of which the misuse is having or appears to it capable of having harmful effects sufficient to constitute a social problem, and to give to any one or more of the ministers⁴, where either the Advisory Council considers it expedient to do so or it is consulted by the minister or ministers in question, advice on measures, whether or not involving alteration of the law, which in the Advisory Council's opinion ought to be taken for preventing the misuse of such drugs or dealing with social problems connected with their misuse⁵, and in particular on measures which in its opinion ought to be taken: (1) for restricting the availability of such drugs or supervising the arrangements for their supply⁶; (2) for enabling persons affected by the misuse of such drugs to obtain proper advice, and for securing the provision of proper facilities and services for their treatment, rehabilitation and after-care⁷; (3) for promoting co-operation between the various professional and community services which in the Advisory Council's opinion have a part to play in dealing with social problems connected with the misuse of such drugs⁸; (4) for educating the public, particularly the young, in the dangers of misusing such drugs, and for giving publicity to those dangers⁹; and (5) for promoting research into, or otherwise obtaining information about, any matter which in the Advisory Council's opinion is of relevance for the purpose of preventing the misuse of such drugs or dealing with any social problem connected with their misuse¹⁰.

It is also the Advisory Council's duty to consider any matter relating to drug dependence or the misuse of drugs which may be referred to it by any one or more of the ministers and to advise the minister or ministers in question thereon, and in particular to consider and advise the Secretary of State¹¹ with respect to any communication referred by him to the Advisory Council, being a communication relating to the control of any dangerous or otherwise harmful drug made to the government by any organisation or authority established by or under any treaty, convention or other agreement or arrangement to which the government is for the time being a party¹².

1 For the meaning of 'the Advisory Council' see PARA 246 note 1 ante. As to the constitution and procedure of the Advisory Council see PARA 246 ante.

2 For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

3 As to references to misusing a drug see PARA 246 note 5 ante.

4 As to the meaning of 'the ministers' for these purposes see the Misuse of Drugs Act 1971 s 1(4); Northern Ireland Act 1998 s 95(5), Sch 12 para 10. All functions of a Minister of the Crown under the Misuse of Drugs Act 1971 s 1, so far as exercisable in respect of Wales, are transferred to the National Assembly for Wales: see the National Assembly for Wales (Transfer of Functions) Order 1999, SI 1999/672, art 2, Sch 1. For the meanings of 'England' and 'Wales' see PARA 7 note 3 ante. As to the National Assembly for Wales and as to government in Northern Ireland see CONSTITUTIONAL LAW AND HUMAN RIGHTS.

5 Misuse of Drugs Act 1971 s 1(2).

6 Ibid s 1(2)(a).

7 Ibid s 1(2)(b).

8 Ibid s 1(2)(c).

- 9 Ibid s 1(2)(d).
- 10 Ibid s 1(2)(e).
- 11 As to the Secretary of State see PARA 3 note 3 ante.
- 12 Misuse of Drugs Act 1971 s 1(3).

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(3) THE CONTROL OF DRUGS/(i) Prohibitions and Offences/248. Restrictions on importation and exportation.

(3) THE CONTROL OF DRUGS

(i) Prohibitions and Offences

248. Restrictions on importation and exportation.

The importation of a controlled drug¹ and the exportation of a controlled drug² are both prohibited³. This does not, however, apply to the importation or exportation of a controlled drug which is excepted from the prohibition by regulations⁴ or to the importation or exportation under and in accordance with the terms of a licence issued by the Secretary of State and in compliance with any conditions attached to the licence⁵.

1 Misuse of Drugs Act 1971 s 3(1)(a). For the meaning of 'controlled drug' see PARA 238 ante.

2 Ibid s 3(1)(b).

3 Ibid s 3(1). Goods imported contrary to any prohibition are subject to forfeiture under the Customs and Excise Management Act 1979 s 49(1)(b) (see CUSTOMS AND EXCISE vol 12(3) (2007 Reissue) PARA 993); and goods exported or brought to any place in the United Kingdom for the purpose of being exported contrary to any prohibition are subject to forfeiture under s 68(1) (as amended) (see CUSTOMS AND EXCISE vol 12(3) (2007 Reissue) PARA 1029). For the meaning of 'United Kingdom' see PARA 7 note 3 ante. The penalties for these offences set out in s 50 (as amended) (importation) (see CUSTOMS AND EXCISE vol 12(3) (2007 Reissue) PARA 994), s 68 (as amended) (exportation) (see CUSTOMS AND EXCISE vol 12(3) (2007 Reissue) PARA 1029) and s 170 (as amended) (fraudulent evasion of duty) (see CUSTOMS AND EXCISE vol 12(3) (2007 Reissue) PARA 1178) are modified in respect of controlled drugs as follows: where such offences are concerned with Class A or Class B drugs (see PARAS 238-240 ante), a person is liable on conviction on indictment, where the goods are a Class A drug, to a penalty of any amount or to imprisonment for life or to both and, where the goods are a Class B drug, to a penalty of any amount or to imprisonment for a term not exceeding 14 years or to both, and on summary conviction to a penalty of the prescribed sum or of three times the value of the goods, whichever is greater, or to imprisonment for a term not exceeding six months or to both: ss 50(5), 68(4), 170(4), Sch 1 para 1 (amended by the Controlled Drugs (Penalties) Act 1985 s 1(2)). As to the prescribed sum see PARA 32 note 3 ante. In a case concerning a Class C drug (see PARAS 238, 241 ante), a person is liable on conviction on indictment to imprisonment for a term not exceeding 14 years or to a penalty of any amount or to both, or on summary conviction to a penalty of three times the value of the goods or level 5 on the standard scale, whichever is greater, or to imprisonment for a term not exceeding three months or to both: Customs and Excise Management Act 1979 Sch 1 para 2 (amended by virtue of the Criminal Justice Act 1982 s 46; and the Criminal Justice Act 2003 s 284, Sch 28 para 2). As to the standard scale see PARA 6 note 22 ante. It is not a defence to such an offence that the importation of the drug was for the purpose of its use for the alleviation of pain in seriously ill persons: *R v Quayle* [2005] EWCA Crim 1415, (2005) Times, 22 June, [2005] All ER (D) 447 (May). As to sentence see *R v Coughlan* (1994) 16 Cr App Rep (S) 519, (1994) Times, 31 October, CA. See also *R v Yalman* [1998] 2 Cr App Rep 269, [1998] Crim LR 569, CA (evidence of past drug use relevant to rebut defendant's claim of innocence in respect of importation). As to incitement to commit offences under the Misuse of Drugs Act 1971 and as to persons assisting in or inducing the commission of offences under comparable foreign legislation see PARA 260 post. As to the power of the Secretary of State to exclude the application of the Customs and Excise Management Act 1979 s 50(1)-(4) (as amended), s 68(2), (3) (as amended), s 170 (as amended) in prescribed cases see the Misuse of Drugs Act 1971 s 22 (as amended); and PARA 243 ante. As to the Secretary of State see PARA 3 note 3 ante.

An offence under the Customs and Excise Management Act 1979 s 50(2), (3) (as amended), s 68(2) (as amended), s 170 (as amended), in connection with a prohibition or restriction on importation or exportation having effect by virtue of the Misuse of Drugs Act 1971 s 3, is a 'lifestyle offence' for the purposes of the Proceeds of Crime Act 2002 ss 75, 223: see SENTENCING AND DISPOSITION OF OFFENDERS vol 92 (2010) PARA 393. For the power of the court to impose a travel banning order on an individual convicted of such an offence in connection with a prohibition or restriction on importation or exportation having effect by virtue of the Misuse of Drugs Act 1971 s 3 see the Criminal Justice and Police Act 2001 ss 33-37; and SENTENCING AND DISPOSITION OF OFFENDERS vol 92 (2010) PARAS 372-374. Such offences, in connection with a prohibition or restriction on

importation or exportation having effect by virtue of the Misuse of Drugs Act 1971 s 3, are excluded offences for the purposes of the Criminal Justice Act 1982 s 32 (as amended) (early release of prisoners): see s 32(2)(c), Sch 1 Pt III; and PRISONS vol 36(2) (Reissue) PARA 613.

4 Misuse of Drugs Act 1971 s 3(2)(a). The regulations referred to in the text are any made under s 7: see PARA 259 post. As to the making of regulations see PARA 242 ante. The restrictions on importation and exportation of controlled drugs are not to have effect in relation to the controlled drugs specified in the Misuse of Drugs Regulations 2001, SI 2001/3998, Schs 4, 5 (Sch 4 amended by SI 2003/1432). See *R v Hunt* [1987] AC 352, [1987] 1 All ER 1, HL; and PARA 259 post.

5 Misuse of Drugs Act 1971 s 3(2)(b). As to the issue of licences see s 7(2); and PARA 259 post. See *R v Secretary of State for the Home Department, ex p Arthur H Cox & Co Ltd* (1998) 46 BMLR 144 (refusal to grant licence for importation from more than one country justified). The Misuse of Drugs Act 1971 provides for an offence of contravening a term or condition of a licence (see PARA 260 post), and places the onus of proving that the defendant had a licence on the defendant. It would appear that he discharges this burden by proof on a balance of probabilities: *R v Ewens* [1967] 1 QB 322, [1966] 2 All ER 470, CCA. See also *Wood v Allan* 1988 SLT 341; *R v Oliver* [1944] KB 68, [1943] 2 All ER 800, CCA; and CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(3) (2006 Reissue) PARA 1372.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

248 Restrictions on importation and exportation

NOTE 4--SI 2001/3998 Sch 4 further amended: SI 2005/3372, SI 2007/2154, SI 2009/3136. SI 2001/3998 Sch 5 amended: SI 2005/2864.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(3) THE CONTROL OF DRUGS/(i) Prohibitions and Offences/249. Restrictions on production and supply.

249. Restrictions on production and supply.

Subject to any regulations¹ for the time being in force, it is not lawful for a person² to produce³ a controlled drug⁴, or to supply⁵ or offer to supply a controlled drug to another⁶. It is an offence⁷ for a person⁸:

- 226 (1) to produce a controlled drug in contravention⁹ of this prohibition¹⁰; or
- 227 (2) to be concerned in the production of such a drug in contravention of this prohibition by another¹¹;
- 228 (3) to supply or offer to supply¹² a controlled drug to another in contravention of this prohibition¹³; or
- 229 (4) to be concerned in the supplying of such a drug to another in contravention of this prohibition¹⁴; or
- 230 (5) to be concerned in the making to another in contravention of this prohibition of an offer to supply such a drug¹⁵.

1 In the Misuse of Drugs Act 1971 s 7 (see PARA 259 post). See PARAS 250-251 post.

2 For the meaning of 'person' see PARA 21 note 7 ante.

3 'Produce', where the reference is to producing a controlled drug, means producing it by manufacture, cultivation or any other method; and 'production' has a corresponding meaning: Misuse of Drugs Act 1971 s 37(1). For the meaning of 'controlled drug' see PARA 238 ante. For a person to be convicted of production there must be some identifiable participation in the process of producing a controlled drug: *R v Farr* [1982] Crim LR 745, CA. The offence of conspiracy to produce a controlled drug is not committed where the defendants agree to produce a drug in a particular way but the factual circumstances are such that it is not possible to achieve the object by that course of action: *DPP v Nock* [1978] AC 979, [1978] 2 All ER 654, HL (distinguishing *Haggard v Mason* [1976] 1 All ER 337, [1976] 1 WLR 187, where the offence of offering to supply a controlled drug was completed). See note 12 infra.

4 Misuse of Drugs Act 1971 s 4(1)(a). Section 4(1) does not have effect in relation to poppy-straw or any exempt product: Misuse of Drugs Regulations 2001, SI 2001/3998, reg 4(4), (5). For the meaning of 'poppy-straw' see PARA 239 note 7 ante. 'Exempt product' means a preparation or other product consisting of one or more component parts, any of which contains a controlled drug, where: (1) the preparation or other product is not designed for administration of the controlled drug to a human being or animal; (2) the controlled drug in any component part is packaged in such a form, or in combination with other active or inert substances in such a manner, that it cannot be recovered by readily applicable means or in a yield which constitutes a risk to health; and (3) no one component part of the product or preparation contains more than one milligram of the controlled drug or one microgram in the case of lysergide or any other *N*-alkyl derivative of lysergamide: reg 2(1).

5 'Supplying' includes distributing: Misuse of Drugs Act 1971 s 37(1). A person who injects another with the latter's heroin is not supplying it: *R v Harris* [1968] 2 All ER 49n, [1968] 1 WLR 769, CA.

6 Misuse of Drugs Act 1971 s 4(1)(b). See also note 4 supra. Notwithstanding the provisions of s 4(1)(b): (1) any person who is lawfully in possession of a controlled drug may supply that drug to the person from whom he obtained it (Misuse of Drugs Regulations 2001, SI 2001/3998, reg 6(1)); (2) any person who has in his possession a drug specified in Schs 2-5 (Schs 2, 4 amended by SI 2003/1432) which has been supplied by or on the prescription of a practitioner, a registered nurse, a supplementary prescriber or a person specified in the Misuse of Drugs Regulations 2001, SI 2001/3998, Sch 8 (amended by SI 2003/2429; SI 2004/1771) for the treatment of that person, or of a person whom he represents, may supply that drug to any doctor, dentist or pharmacist for the purpose of destruction (Misuse of Drugs Regulations 2001, SI 2001/3998, reg 6(2) (amended by SI 2003/2429; SI 2004/1771; SI 2005/271)); (3) any person who is lawfully in possession of a drug specified in the Misuse of Drugs Regulations 2001, SI 2001/3998, Schs 2-5 (Schs 2, 4 as so amended) which has been supplied by or on the prescription of a veterinary practitioner or veterinary surgeon for the treatment of animals

may supply that drug to any veterinary practitioner, veterinary surgeon or pharmacist for the purpose of destruction (reg 6(3)); (4) any of the following persons, namely, a constable when acting in the course of his duty as such, a person engaged in the business of a carrier when acting in the course of that business, a person engaged in the business of a postal operator (within the meaning of the Postal Services Act 2000: see POST OFFICE) when acting in the course of that business, an officer of customs and excise when acting in the course of his duty as such, a person engaged in the work of any laboratory to which the drug has been sent for forensic examination when acting in the course of his duty as a person so engaged, or a person engaged in conveying the drug to a person who may lawfully have that drug in his possession, may supply any controlled drug to any person who may lawfully have that drug in his possession (Misuse of Drugs Regulations 2001, SI 2001/3998, reg 6(5), (7) (amended by SI 2003/1653)).

7 le subject to the Misuse of Drugs Act 1971 s 28 (defence of lack of knowledge): see PARA 262 post.

8 Where a Class A drug or a Class B drug (see PARAS 238-240 ante) is involved, a person is liable on summary conviction to imprisonment for a term not exceeding six months or to a fine not exceeding the prescribed sum or to both, or on conviction on indictment to imprisonment for life or a fine in the case of a Class A drug or for a term not exceeding 14 years in the case of a Class B drug, or to a fine or to both: *ibid* s 25(1), (2), Sch 4 (amended by the Magistrates' Courts Act 1980 ss 31 (1)-(3), 32; and the Controlled Drugs (Penalties) Act 1985 s 1(1)). As to the prescribed sum see PARA 32 note 3 ante. In a case concerning a Class C drug (see PARAS 238, 241 ante), the offender is liable on summary conviction to imprisonment for a term not exceeding three months or to a fine not exceeding £2,500 or to both, or on conviction on indictment to imprisonment for a term not exceeding 14 years or to a fine or to both: Misuse of Drugs Act 1971 Sch 4 (amended by the Criminal Law Act 1977 s 28(8), Sch 5; the Criminal Justice and Public Order Act 1994 s 157(2), (4), Sch 8 Pt II; and the Criminal Justice Act 2003 s 284, Sch 28 para 1).

As to the offence of incitement to commit these offences see PARA 260 post. As to powers of entry and search and as to forfeiture of drugs see PARA 279 et seq post. For the power of the court to impose a travel banning order on an individual convicted of an offence under the Misuse of Drugs Act 1971 s 4(2), (3) see the Criminal Justice and Police Act 2001 ss 33-37; and SENTENCING AND DISPOSITION OF OFFENDERS vol 92 (2010) PARAS 372-374. An offence under the Misuse of Drugs Act 1971 s 4(2), (3) is a 'lifestyle offence' for the purposes of the Proceeds of Crime Act 2002 ss 75, 223: see SENTENCING AND DISPOSITION OF OFFENDERS vol 92 (2010) PARA 393. Certain categories of offence under the Misuse of Drugs Act 1971 s 4(2), (3) are qualifying offences for the purposes of the Criminal Justice Act 2003 Pt 9 (ss 57-74) (appeals by the prosecution), and Pt 10 (ss 75-97) (retrial of serious offences): see ss 62, 75, Sch 4 Pt 1 paras 22, 23, Sch 5 Pt 1 para 21; and CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(4) (2006 Reissue) PARAS 1914, 1937. An offence under the Misuse of Drugs Act 1971 s 4(2), (3) is a 'relevant offence' for the purposes of the Licensing Act 2003 Pt 6 (ss 111-135) (personal licences): see s 113, Sch 4 para 7; and LICENSING AND GAMBLING vol 67 (2008) PARA 117. As to the power of a constable to enter and search club premises where he has reasonable cause to believe an offence under the Misuse of Drugs Act 1971 s 4(3) has been, is being or is about to be committed see the Licensing Act 2003 s 97; and LICENSING AND GAMBLING vol 67 (2008) PARA 106. An offence under the Misuse of Drugs Act 1971 s 4(2), (3) is an excluded offence for the purposes of the Criminal Justice Act 1982 s 32 (early release of prisoners): see s 32(2)(c), Sch 1 Pt III; and PRISONS vol 36(2) (Reissue) PARA 613.

9 'Contravention' includes failure to comply; and 'contravene' has a corresponding meaning: Misuse of Drugs Act 1971 s 37(1).

10 *Ibid* s 4(2)(a). It is not a defence to such an offence that production was out of medical necessity and for the purpose of the alleviation of pain: *R v Quayle* [2005] EWCA Crim 1415, (2005) Times, 22 June, [2005] All ER (D) 447 (May).

11 Misuse of Drugs Act 1971 s 4(2)(b).

12 The offence of offering to supply a controlled drug is committed even if the substance supplied is not a controlled drug: *Haggard v Mason* [1976] 1 All ER 337, [1976] 1 WLR 187, DC. It is no defence that the offeror had no intention to carry the offer into effect; the offence is complete at the time the offer is made: *R v Goodard* [1992] Crim LR 588, CA; *R v Prior* [2004] EWCA Crim 1147, [2004] Crim LR 849 (in which the court also held that once an offer is made any later withdrawal of it does not cancel out the original offer). As to this offence, and for further cases, see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARA 772.

13 Misuse of Drugs Act 1971 s 4(3)(a). As from a day to be appointed, the following provisions have effect. If a court is considering the seriousness of an offence under s 4(3), and at the time the offence was committed the offender had attained the age of 18 (s 4A(1) (s 4A prospectively added by the Drugs Act 2005 ss 1, 24(3)) and either of the following conditions is met, the court must treat the fact that the condition is met as an aggravating factor (that is to say, a factor that increases the seriousness of the offence) (s 4A(2)(a) (as so prospectively added)), and must state in open court that the offence is so aggravated (s 4A(2)(b) (as so prospectively added)). The first condition is that the offence was committed on or in the vicinity of school premises at a relevant time (s 4A(3) (as so prospectively added)); and the second condition is that in connection with the commission of the offence the offender used a courier who, at the time the offence was committed, was under the age of 18 (s 4A(4) (as so prospectively added)). A 'relevant time' is any time when

the school premises are in use by persons under the age of 18 (s 4A(5)(a) (as so prospectively added)); and one hour before the start and one hour after the end of any such time (s 4A(5)(b) (as so prospectively added)). A person uses a courier in connection with an offence under s 4(3) if he causes or permits another person (the courier) to deliver a controlled drug to a third person (s 4A(6)(a) (as so prospectively added)), or to deliver a drug related consideration to himself or a third person (s 4A(6)(b) (as so prospectively added)). For these purposes, a drug related consideration is a consideration of any description which is obtained in connection with the supply of a controlled drug (s 4A(7)(a) (as so prospectively added)), or is intended to be used in connection with obtaining a controlled drug (s 4A(7)(b) (as so prospectively added)). 'School premises' means land used for the purposes of a school excluding any land occupied solely as a dwelling by a person employed at the school; and 'school' has the same meaning as in the Education Act 1996 s 4 (see EDUCATION vol 15(1) (2006 Reissue) PARA 81); Misuse of Drugs Act 1971 s 4A(8) (as so prospectively added). At the date at which this volume states the law, no day had been appointed for the commencement of these provisions.

14 Ibid s 4(3)(b). See also note 13 supra.

15 Ibid s 4(3)(c). See also note 13 supra. This offence is particularly widely drawn so as to involve people who may be at some distance from the actual making of the offer: *R v Blake, R v O'Connor* (1978) 68 Cr App Rep 1. For further cases see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARA 772.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

249 Restrictions on production and supply

NOTE 6--SI 2001/3998 Sch 3 amended, Sch 8 further amended: SI 2007/2154. SI 2001/3998 Schs 4, 5 further amended: see PARA 248 NOTE 4.

NOTE 13--Day now appointed: SI 2005/3053.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(3) THE CONTROL OF DRUGS/(i) Prohibitions and Offences/250. Persons authorised to produce controlled drugs.

250. Persons authorised to produce controlled drugs.

Notwithstanding the general prohibition¹ on the production of controlled drugs², a practitioner³ or pharmacist⁴ acting in his capacity as such⁵, and a person lawfully conducting a retail pharmacy business⁶ and acting in his capacity as such and at the registered pharmacy⁷ at which he carries on that business⁸, may manufacture or compound any specified drug⁹; and a person who is authorised by a written authority issued¹⁰ by the Secretary of State¹¹ and for the time being in force may, at the premises specified in that authority and in compliance with any conditions so specified, produce any specified drug¹².

Where any person is authorised by a licence¹³ of the Secretary of State for the time being in force to produce any controlled drug, it is not¹⁴ unlawful for that person to produce that drug in accordance with the terms of the licence and in compliance with any conditions attached to the licence¹⁵.

1 Ie under the Misuse of Drugs Act 1971 s 4(1)(a): see PARA 249 ante.

2 For the meaning of 'controlled drug' see PARA 238 ante.

3 For the meaning of 'practitioner' see PARA 243 note 9 ante.

4 For the meaning of 'pharmacist' see PARA 46 note 10 ante.

5 Misuse of Drugs Regulations 2001, SI 2001/3998, regs 8(1)(a), 9(1)(a).

6 'Person lawfully conducting a retail pharmacy business' means a person lawfully conducting such a business in accordance with the Medicines Act 1968 s 69 (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 909): Misuse of Drugs Act 1971 s 37(1) (definition amended by the Statute Law (Repeals) Act 2004).

7 For the meaning of 'registered pharmacy' see PARA 51 note 3 ante; definition applied by the Misuse of Drugs Regulations 2001, SI 2001/3998, reg 2(1).

8 Ibid regs 8(1)(b), 9(1)(b).

9 Ibid regs 8(1)(a), (b), 9(1)(a), (b). As to the specified drugs see Schs 2-5 (Schs 2, 4 amended by SI 2003/1432).

10 Ie under and for the purposes of Misuse of Drugs Regulations 2001, SI 2001/3998, reg 9(1)(c).

11 As to the Secretary of State see PARA 3 note 3 ante.

12 Misuse of Drugs Regulations 2001, SI 2001/3998, reg 9(1)(c). As to the specified drugs see Schs 3, 4 (Sch 4 amended by SI 2003/1432). Such a person may also supply or offer to supply certain controlled drugs: see PARA 251 head (g) post.

13 Ie issued under the Misuse of Drugs Regulations 2001, SI 2001/3998, reg 5.

14 Ie by virtue of the Misuse of Drugs Act 1971 s 4(1): see PARA 249 ante.

15 Misuse of Drugs Regulations 2001, SI 2001/3998, reg 5. As to licences generally see PARA 244 ante. As to the offence of contravening a term of a licence see the Misuse of Drugs Act 1971 s 18(2); and PARA 260 post.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

250 Persons authorised to produce controlled drugs

NOTE 9--SI 2001/3998 Sch 3 amended: see PARA 249 NOTE 6. SI 2001/3998 Schs 4, 5 further amended: see PARA 248 NOTE 4.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(3) THE CONTROL OF DRUGS/(i) Prohibitions and Offences/251. Persons authorised to supply controlled drugs.

251. Persons authorised to supply controlled drugs.

Notwithstanding the general prohibition¹ on the supplying or offering for supply of controlled drugs² any of the following persons, namely:

- 231 (1) a practitioner³;
- 232 (2) a pharmacist⁴;
- 233 (3) a person lawfully conducting a retail pharmacy business⁵;
- 234 (4) the person in charge or acting person in charge of a hospital or nursing home which is wholly or mainly maintained by a public authority out of public funds or by a charity or by voluntary subscriptions⁶;
- 235 (5) in the case of such a drug supplied by a person responsible for the dispensing and supply of medicines at the hospital or nursing home, the sister or acting sister⁷ for the time being in charge of a ward, theatre or other department in such a hospital or nursing home⁸;
- 236 (6) a person who is in charge of a laboratory the recognised activities of which consist in, or include, the conduct of scientific education or research and which is attached to a university, university college or such a hospital or to any other institution approved for these purposes by the Secretary of State⁹;
- 237 (7) a public analyst¹⁰;
- 238 (8) a sampling officer¹¹;
- 239 (9) a person employed or engaged in connection with a scheme for testing the quality or amount of the drugs, preparations and appliances supplied under the National Health Service Act 1977 and the regulations made thereunder¹²;
- 240 (10) a person authorised¹³ by the Pharmaceutical Society of Great Britain¹⁴;
- 241 (11) a supplementary prescriber acting under and in accordance with the terms of a clinical management plan¹⁵,

may, when acting in his capacity as such, supply or offer to supply any specified drug¹⁶ to any person who may lawfully have that drug in his possession¹⁷.

There are also exceptions in respect of the supply or offer to supply of any specified drug to any person who may lawfully have that drug in his possession, in the case of: (a) a person who is authorised as a member of a group who acts under and in accordance with the terms of his group authority and in compliance with any conditions attached thereto¹⁸; (b) a person who is authorised by a written authority issued¹⁹ by the Secretary of State, and for the time being in force, at the premises specified in that authority and in compliance with any conditions so specified²⁰; (c) the owner of a ship, or the master of a ship which does not carry a doctor among the seamen employed in it, or the installation manager of an offshore installation²¹; (d) an extended formulary nurse prescriber²²; (e) a registered nurse²³; (f) certain other health professionals²⁴; (g) a person who is authorised²⁵ to produce controlled drugs, in respect of any drug which he may, by virtue of being so authorised, lawfully produce²⁶; (h) a person in charge of a laboratory, when acting in his capacity as such, in respect of any specified drug which is required for use as a buffering agent in chemical analysis²⁷; (i) a registered midwife²⁸.

Provision is also made as to the lawful administration of controlled drugs²⁹.

Where any person is authorised by a licence³⁰ of the Secretary of State, for the time being in force, to supply or offer to supply any controlled drug, it is not unlawful for that person to

supply or offer to supply that drug in accordance with the terms of the licence and in compliance with any conditions attached to the licence³¹.

1 le under the Misuse of Drugs Act 1971 s 4(1)(b): see PARA 249 ante.

2 For the meaning of 'controlled drug' see PARA 238 ante.

3 Misuse of Drugs Regulations 2001, SI 2001/3998, regs 8(2)(a), 9(2)(a). For the meaning of 'practitioner' see PARA 243 note 9 ante.

4 Ibid regs 8(2)(b), 9(2)(b). For the meaning of 'pharmacist' see PARA 46 note 10 ante.

5 Ibid regs 8(2)(c), 9(2)(c). For the meaning of 'a person lawfully conducting a retail pharmacy business' see PARA 250 note 6 ante.

6 Ibid reg 8(2)(d). See also note 17 infra.

7 'Sister or acting sister' includes any male nurse occupying a similar position: ibid reg 2(1).

8 Ibid reg 8(2)(e). See also note 17 infra.

9 Ibid regs 8(2)(f), 9(2)(d). In the case of reg 9(2)(d) it is not necessary that the laboratory be attached to a university, university college, hospital or any other institution: see reg 9(2)(d). As to the Secretary of State see PARA 3 note 3 ante.

10 Ibid regs 8(2)(g), 9(2)(e). A public analyst is one appointed under the Food Safety Act 1990 s 27 (see FOOD vol 18(2) (Reissue) PARA 268): Misuse of Drugs Regulations 2001, SI 2001/3998, regs 8(2)(g), 9(2)(e).

11 Ibid regs 8(2)(h), 9(2)(f). A sampling officer is one within the meaning of the Medicines Act 1968 Sch 3 (see PARA 171 ante): Misuse of Drugs Regulations 2001, SI 2001/3998, regs 8(2)(h), 9(2)(f).

12 Ibid regs 8(2)(i), 9(2)(g).

13 le for the purposes of the Medicines Act 1968 s 108: see PARA 168 ante.

14 Misuse of Drugs Regulations 2001, SI 2001/3998, regs 8(2)(j), 9(2)(h). As to the Pharmaceutical Society of Great Britain see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 881 et seq.

15 Ibid regs 8(2)(k), 9(2)(i) (both added by SI 2005/271). 'Supplementary prescriber' and 'clinical management plan' have the same meanings as in the Prescription Only Medicines (Human Use) Order 1997, SI 1997/1830: Misuse of Drugs Regulations 2001, SI 2001/3998, reg 2(1) (definitions added by SI 2005/271). 'Supplementary prescriber' means (1) a first level nurse; (2) a pharmacist; (3) a registered midwife; (4) a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of the Health Professions Order 2001, SI 2002/254, art 5 (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 325) relating to chiropodists and podiatrists, physiotherapists, or radiographers: diagnostic or therapeutic; or (5) a registered optometrist, against whose name is recorded in the relevant register an annotation or entry signifying that he is qualified to order drugs, medicines and appliances as a supplementary prescriber: Prescription Only Medicines (Human Use) Order 1997, SI 1997/1830, art 1(2) (definition added by SI 2003/696, and amended by SI 2004/1771, SI 2005/765, SI 2005/1507). 'First level nurse' means a person registered in Sub-Part 1 of the Nurses' Part of the professional register; and 'registered midwife' means a person registered in the Midwives' Part of that register: Prescription Only Medicines (Human Use) Order 1997, SI 1997/1830, art 1(2) (definitions added by SI 2004/1771). 'Professional register' means the register maintained by the Nursing and Midwifery Council under the Nursing and Midwifery Order 2001, SI 2002/253, art 5 (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 717): Prescription Only Medicines (Human Use) Order 1997, SI 1997/1830, art 1(2) (definition added by SI 2002/549, and amended by SI 2004/1771). 'Registered optometrist' means a person whose name is registered in the register of optometrists maintained under the Opticians Act 1989 s 7(a) (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 838): Prescription Only Medicines (Human Use) Order 1997, SI 1997/1830, art 1(2) (definition added by SI 2005/848). 'Relevant register' means (a) in relation to a first level nurse or registered midwife, the professional register; (b) in relation to a pharmacist, the register maintained in pursuance of the Pharmacy Act 1954 s 2(1) (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 888); (c) in relation to a person whose name is registered in the part of the register maintained by the Health Professions Council in pursuance of the Health Professions Order 2001, SI 2002/254, art 5 relating to chiropodists and podiatrists, physiotherapists or radiographers: diagnostic or therapeutic, that register; and (d) in relation to a registered optometrist, the register of optometrists maintained under the Opticians Act 1989 s 7(a): Prescription Only Medicines (Human Use) Order 1997, SI 1997/1830, art 1(2) (definition amended by SI 2004/1771, SI 2005/765, SI 2005/1507). 'Clinical management plan' means a written plan (which may be amended from time to time) relating to the treatment of an individual patient agreed by (i) the patient to whom the plan relates, (ii) the

doctor or dentist who is a party to the plan, and (iii) any supplementary prescriber who is to prescribe, give directions for administration or administer under the plan: Prescription Only Medicines (Human Use) Order 1997, SI 1997/1830, art 1(2) (definition added by SI 2003/696).

16 As to the specified drugs see the Misuse of Drugs Regulations 2001, SI 2001/3998, Schs 2, 5 (Sch 2 amended by SI 2003/1432). The persons specified in heads (1)-(3), (6)-(11) in the text may also, when acting in their capacity as such, supply or offer to supply any drug specified in the Misuse of Drugs Regulations 2001, SI 2001/3998, Schs 3, 4 (Sch 4 amended by SI 2003/1432) to any person who may lawfully have that drug in his possession: Misuse of Drugs Regulations 2001, SI 2001/3998, reg 9(2). The person in charge or acting person in charge of a hospital or nursing home and a person specified in head (5) in the text may, when acting in his capacity as such and subject to certain conditions, supply or offer to supply any drug specified in Sch 3 or any drug specified in Sch 4 (as so amended) which is contained in a medicinal product: see reg 9(3)(b), (c). For the meaning of 'medicinal product' see PARA 7 ante; definition applied by reg 2(1).

17 Ibid regs 8(2), 9(2). However, nothing in reg 8(2) authorises: (1) the person in charge or acting person in charge of a hospital or nursing home, having a pharmacist responsible for the dispensing and supply of medicines, to supply or offer to supply any drug (reg 8(2)(i)); or (2) a sister or acting sister for the time being in charge of a ward, theatre or other department to supply any drug otherwise than for administration to a patient in that ward, theatre or department in accordance with the directions of a doctor or dentist (reg 8(2)(ii)). For the meanings of 'doctor' and 'dentist' see PARA 243 note 9 ante.

18 See ibid regs 8(3), 9(3)(a). As to the specified drugs for the purposes of reg 8(3) see Schs 2, 5 (Sch 2 as amended: see note 16 supra); and as to the specified drugs for the purposes of reg 9(3) see Sch 3 and any drug specified in Sch 4 (as amended: see note 16 supra) which is contained in a medicinal product.

19 Ie under and for the purposes of ibid regs 8(4), 9(4)(a).

20 Ibid reg 8(4), 9(4)(a). As to the specified drugs in the case of an authority under reg 8(4) see Sch 5; and as to the specified drugs in the case of an authority under reg 9(4)(a) see Schs 3, 4 (as amended: see note 16 supra).

21 See ibid regs 8(5), 9(5). Certain conditions must be met for the supply to be lawful: see regs 8(5), (6), 9(5). As to the specified drugs for the purposes of reg 8(5) see Schs 2, 5 (Sch 2 as amended: see note 16 supra); and as to the specified drugs for the purposes of reg 9(5) see Schs 3, 4 (as amended: see note 16 supra). 'Master' and 'seamen' have the same meanings as in the Merchant Shipping Act 1995 (see SHIPPING AND MARITIME LAW vol 93 (2008) PARA 424); Misuse of Drugs Regulations 2001, SI 2001/3998, reg 2(1). 'Installation manager' and 'offshore installation' have the same meanings as in the Mineral Workings (Offshore Installations) Act 1971 (see FUEL AND ENERGY vol 19(3) (2007 Reissue) PARAS 1684, 1685); Misuse of Drugs Regulations 2001, SI 2001/3998, reg 2(1).

22 See ibid regs 8(7), 9(7) (regs 8(7), 9(7) added by SI 2003/2429). Any supply is subject to certain conditions and relates to certain drugs only: see the Misuse of Drugs Regulations 2001, SI 2001/3998, regs 8(7), 9(7). 'Extended formulary nurse prescriber' has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997, SI 1997/1830; and such a person may only prescribe: (1) diazepam, lorazepam or midazolam for use in palliative care; (2) codeine phosphate, dihydrocodeine tartrate or co-phenotrope: Misuse of Drugs Regulations 2001, SI 2001/3998, reg 2(1). 'Extended formulary nurse prescriber' means a person who is a first level nurse or registered midwife, and against whose name is recorded in the professional register an annotation signifying that he is qualified to order drugs, medicines and appliances from the Extended Formulary: Prescription Only Medicines (Human Use) Order 1997, SI 1997/1830, art 1(2) (definition added by SI 2002/549, and amended by SI 2003/696, SI 2004/1771). 'Extended Formulary' means the Nurse Prescribers' Extended Formulary Appendix in the current edition of the British National Formulary: Prescription Only Medicines (Human Use) Order 1997, SI 1997/1830, art 1(2) (definition added by SI 2002/549).

23 See the Misuse of Drugs Regulations 2001, SI 2001/3998, regs 8(8)(a), (b), 9(8) (regs 8(8), 9(8) added by SI 2003/2429). 'Registered nurse' has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997, SI 1997/1830: Misuse of Drugs Regulations 2001, SI 2001/3998, reg 2(1). 'Registered nurse' means a person registered in the Nurses' Part of the professional register (see note 15 supra): Prescription Only Medicines (Human Use) Order 1997, SI 1997/1830, art 1(2) (definition substituted by SI 2004/1771).

24 See ibid regs 8(8)(b), 9(8), Sch 8 (regs 8(8), 9(8) as added (see note 23 supra); and Sch 8 added by SI 2003/2429; and amended by SI 2004/1771).

25 Ie under the Misuse of Drugs Regulations 2001, SI 2001/3998, reg 9(1)(c): see PARA 250 ante.

26 Ibid reg 9(4)(b).

27 Ibid reg 9(6), Sch 3.

28 See *ibid* reg 11 (amended by SI 2004/1771). 'Registered midwife' has the same meaning as in the Prescription Only Medicines (Human Use) Order 1997, SI 1997/1830 (see note 15 *supra*): Misuse of Drugs Regulations 2001, SI 2001/3998, reg 2(1).

29 See *ibid* reg 7 (amended by SI 2003/2429; SI 2005/271).

30 *Ie* issued under the Misuse of Drugs Regulations 2001, SI 2001/3998, reg 5.

31 *Ibid* reg 5. As to the offence of contravening a term of a licence see the Misuse of Drugs Act 1971 s 18(2); and PARA 260 *post*.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

251 Persons authorised to supply controlled drugs

TEXT AND NOTES--Also, head (12) in the case of such a drug supplied by a person responsible for the dispensing and supply of medicines at a hospital, an operating department practitioner practising in that hospital: SI 2001/3998 reg 8(2)(ea) (added by SI 2007/2154).

TEXT AND NOTE 6--In head (4), for 'nursing home' read 'care home': SI 2001/3998 reg 8(2)(d) (amended by SI 2007/2154).

NOTE 7--Definition of sister or acting sister omitted: SI 2001/3998 reg 2(1) (amended by SI 2007/2154).

TEXT AND NOTE 8--In head (5), for 'nursing home' read 'care home', and for 'sister or acting sister' read 'senior registered nurse or acting senior registered nurse': SI 2001/3998 reg 8(2)(e) (amended by SI 2007/2154).

NOTE 15--Definition of 'supplementary prescriber' amended, definition of 'first level nurse' revoked: SI 2006/915. Definition of 'relevant register' amended: SI 2006/915, SI 2007/289. Definition of 'register optometrist' amended: SI 2007/3101.

NOTE 16-- For 'nursing home' read 'care home': SI 2001/3998 reg 9(3)(b)(c) (amended by SI 2007/2154). As to further provision for the production and supply of drugs, see SI 2001/3998 reg 9(3)(d) (added by SI 2007/2154). SI 2001/3998 Sch 2 further amended: SI 2009/3136. SI 2001/3998 Sch 3 amended: see PARA 249 NOTE 6. SI 2001/3998 Schs 4, 5 further amended: see PARA 248 NOTE 4.

NOTE 17--In head (2), for 'a sister or acting sister' read 'senior registered nurse or acting senior registered nurse', and 'doctor or dentist' read 'doctor, dentist, supplementary prescriber acting under and in accordance with the terms of a clinical management plan, or subject to SI 2001/3998 reg 8(2A), a nurse independent prescriber': reg 8(2)(ii) (amended by SI 2007/2154). Also, head (3) an operating department practitioner to supply any drug otherwise than for administration to a patient in a ward, theatre or other department in accordance with the directions of a doctors, dentist, supplementary prescriber acting under and in accordance with the terms of a clinical management plan or, subject to SI 2001/3998 reg 8(2A), a nurse independent prescriber: reg 8(2)(iii) (added by SI 2007/2154). The directions given by a nurse independent prescriber referred to in SI 2001/3998 reg 8(2)(ii), (iii) relate only to a controlled drug which may be prescribed under reg 6B and for a prescribed purpose: reg 8(2A) (added by SI 2007/2154).

NOTE 18--SI 2001/3998 reg 9(3) amended: SI 2007/2154.

TEXT AND NOTE 22--Now, head (d) a nurse independent prescriber: SI 2001/3998 regs 8(7), 9(7) (substituted by SI 2005/2864 and amended by SI 2006/986). Now, a nurse independent prescriber may only prescribe (1) diamorphine, morphine or oxycodone for use in palliative care; (2) buprenorphine or fentanyl for transdermal use in palliative care; (3) diamorphine or morphine for pain relief in respect of suspected myocardial infarction or for relief of acute or severe pain after trauma including in either case post-operative pain relief; (4) chlordiazepoxide hydrochloride or diazepam for treatment of initial or acute withdrawal symptoms caused by the withdrawal of alcohol from persons habituated to it; and (5) codeine phosphate, dihydrocodeine tartrate or co-phenotrope; and (6) diazepam, lorazepam or midazolam for use in palliative care or treatment of tonic-clonic seizures: SI 2001/3998 reg 6B (added by SI 2005/2864, and amended by SI 2006/986). 'Nurse independent prescriber' has the same meaning as in the Prescriptions Only Medicines (Human Use) Order 1997, SI 1997/1830, and such a person may only prescribe specified controlled drugs: SI 2001/3998 reg 2(1) (amended by SI 2006/986). 'Nurse independent prescriber' means a person (a) who is a registered nurse or a registered midwife, and (b) against whose name is recorded in the professional register an annotation signifying that he is qualified to order drugs, medicines and appliances as a nurse independent prescriber or a nurse independent/supplementary prescriber: SI 1997/1830 art 1(2) (definition added by SI 2006/915). Definitions of 'extended formulary nurse prescriber' and 'Extended Formulary' revoked: SI 2006/915.

NOTE 23--Definition of 'registered nurse' amended: SI 2006/915.

NOTE 24--SI 2001/3998 Sch 8 amended: SI 2007/2154.

NOTE 29--SI 2001/3998 reg 7 further amended: SI 2005/2864, SI 2006/986.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(3) THE CONTROL OF DRUGS/(i) Prohibitions and Offences/252. Restrictions on possession.

252. Restrictions on possession.

Subject to any regulations¹ for the time being in force, it is not lawful for a person to have a controlled drug² in his possession³. It is an offence⁴ for a person to have a controlled drug in his possession in contravention⁵ of this prohibition⁶; and it is also an offence for a person to have a controlled drug in his possession⁷, whether lawfully or not, with intent to supply it⁸ to another⁹.

1 The regulations made under the Misuse of Drugs Act 1971 s 7 (see PARA 259 post). As to such regulations see PARA 253 post.

2 For the meaning of 'controlled drug' see PARA 238 ante.

3 Misuse of Drugs Act 1971 s 5(1). As to the meaning of 'possession' see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARA 771.

Section 5(1) does not have effect in relation to poppy-straw (see PARA 239 note 7 ante) (Misuse of Drugs Regulations 2001, SI 2001/3998, reg 4(4)); and does not have effect in relation to any exempt product (reg 4(5)). For the meaning of 'exempt product' see PARA 249 note 4 ante. The Misuse of Drugs Act 1971 s 5(1) does not have effect in relation to any drug specified in the Misuse of Drugs Regulations 2001, SI 2001/3998, Sch 4 Pt II which is contained in a medicinal product (reg 4(3)(a)); and the drugs specified in Sch 5 (reg 4(3)(b)). For the meaning of 'medicinal product' see PARA 7 ante; definition applied by reg 2(1). The Misuse of Drugs Act 1971 s 5(1) does not have effect in relation to a fungus (of any kind) which contains psilocin or an ester of psilocin where that fungus: (1) is growing uncultivated (Misuse of Drugs Regulations 2001, SI 2001/3998, reg 4A(1)(a) (reg 4A added by SI 2005/1653)); (2) is picked by a person already in lawful possession of it for the purpose of delivering it as soon as is reasonably practicable into the custody of a person lawfully entitled to take custody of it and it remains in that person's possession for and in accordance with that purpose (Misuse of Drugs Regulations 2001, SI 2001/3998, reg 4A(1)(b) (as so added)); (3) is picked for either of the specified purposes and is held for the purpose of destroying the fungus as soon as is reasonably practicable, either by the person who picked it or by another person (reg 4A(1)(c) (as so added)); or (4) is picked for the purpose of destroying the fungus as soon as is reasonably practicable and is held for the purpose of delivering the fungus as soon as is reasonably practicable into the custody of a person lawfully entitled to take custody of it, either by the person who picked it or by another person (reg 4A(1)(d) (as so added)). The specified purposes are: (a) the delivering of the fungus as soon as is reasonably practicable into the custody of a person lawfully entitled to take custody of it (reg 4A(2)(a) (as so added)); and (b) the destroying of the fungus as soon as is reasonably practicable (reg 4A(2)(b) (as so added)).

4 The subject to the Misuse of Drugs Act 1971 s 28 (defence of lack of knowledge): see PARA 262 post.

5 For the meaning of 'contravention' see PARA 249 note 9 ante.

6 Misuse of Drugs Act 1971 s 5(2). In any proceedings for such an offence in which it is proved that the accused had a controlled drug in his possession, it is a defence for him to prove: (1) that, knowing or suspecting it to be a controlled drug, he took possession of it for the purpose of preventing another from committing or continuing to commit an offence in connection with that drug and that as soon as possible after taking possession of it he took all such steps as were reasonably open to him to destroy the drug or to deliver it into the custody of a person lawfully entitled to take custody of it (s 5(4)(a)); or (2) that, knowing or suspecting it to be a controlled drug, he took possession of it for the purpose of delivering it into the custody of a person lawfully entitled to take custody of it and that as soon as possible after taking possession of it he took all such steps as were reasonably open to him to deliver it into the custody of such a person (s 5(4)(b)). Nothing in s 5(4) prejudices any defence which it is open to a person charged with an offence under s 5 to raise apart from that provision: s 5(6) (amended by the Criminal Attempts Act 1981 s 10, Schedule Pt I). It is not a defence to such an offence that possession was out of medical necessity and for the purpose of the alleviation of pain: *R v Quayle* [2005] EWCA Crim 1415, (2005) Times, 22 June, [2005] All ER (D) 447 (May). For further cases on the possession of controlled drugs see further CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARA 770 et seq.

Where a Class A drug (see PARAS 238-239 ante) is involved, a person is liable on summary conviction to imprisonment for a term not exceeding six months or to a fine not exceeding the prescribed sum or to both, or

on conviction on indictment to imprisonment for a term not exceeding seven years or to a fine or to both: Misuse of Drugs Act 1971 s 25(1), (2), Sch 4 (amended by virtue of the Magistrates' Courts Act 1980 ss 31(1)-(3), 32). As to the prescribed sum see PARA 32 note 3 ante. In a case concerning a Class B drug (see PARAS 238, 240 ante), a person is liable on summary conviction to imprisonment for no longer than three months or to a fine of £2,500 or both, or on conviction on indictment to imprisonment for a term not exceeding five years or to a fine or both: see the Misuse of Drugs Act 1971 Sch 4 (amended by the Criminal Law Act 1977 s 28(8), Sch 5; and the Criminal Justice and Public Order Act 1994 s 157(2), (4), Sch 8 Pt II). In a case concerning a Class C drug (see PARAS 238, 241 ante), a person is liable on summary conviction to imprisonment for a term not exceeding three months or to a fine of £1000 or both, or on conviction on indictment to imprisonment for a term not exceeding two years or to a fine or both: Misuse of Drugs Act 1971 Sch 4 (amended by the Criminal Law Act 1977 s 28(8), Sch 5; and the Criminal Justice and Public Order Act 1994 s 157(2), (4), Sch 8 Pt II). As to incitement to commit an offence see PARA 260 post. As to powers of entry and search see PARAS 279-280 post. As to the prosecution of offences in the magistrates' court see PARA 282 post. As to the powers of a court to order forfeiture of anything shown to relate to an offence see PARA 283 post.

7 The things which a person has in his possession are taken to include anything subject to his control which is in the custody of another: Misuse of Drugs Act 1971 s 37(3).

8 In contravention of *ibid* s 4(1): see PARA 249 ante.

9 *Ibid* s 5(3). Where a Class A drug or a Class B drug is involved, a person is liable on summary conviction to imprisonment for a term not exceeding six months or to a fine not exceeding the prescribed sum or to both, or on a conviction on indictment to imprisonment for life in the case of a Class A drug or a term not exceeding 14 years in the case of a Class B drug or to a fine or to both: s 25(1), (2), Sch 4 (amended by virtue of the Magistrates' Courts Act 1980 ss 31(1)-(3), 32); and by the Controlled Drugs (Penalties) Act 1985 s 1(1)). Where a Class C drug is involved, a person is liable on summary conviction to imprisonment for a term not exceeding three months or to a fine of £2,500 or both, or on conviction on indictment to imprisonment for a term not exceeding 14 years or to a fine or both: Misuse of Drugs Act 1971 Sch 4 (amended by the Criminal Law Act 1977 s 28(8), Sch 5; the Criminal Justice and Public Order Act 1994 s 157(2), (4), Sch 8 Pt II; and by the Criminal Justice Act 2003 s 284, Sch 28 para 1). It is not a defence to such an offence that possession was for supply to persons with a medical requirement who might need it to relieve their suffering: *R v Quayle* [2005] EWCA Crim 1415, (2005) Times, 22 June, [2005] All ER (D) 447 (May). For further cases on the possession of drugs see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARA 770 et seq.

As from a day to be appointed, the following provisions have effect. In any proceedings for an offence under s 5(3), if it is proved that the accused had an amount of a controlled drug in his possession which is not less than the prescribed amount, the court or jury must assume that he had the drug in his possession with the intent to supply it to another: s 5(4A) (s 5(4A)-(4C) prospectively added by the Drugs Act 2005 ss 2(1), (2), 24(3)). This provision does not apply if evidence is adduced which is sufficient to raise an issue that the accused may not have had the drug in his possession with that intent: Misuse of Drugs Act 1971 s 5(4B) (as so prospectively added). Regulations under s 5(4A) (prospectively added) have effect only in relation to proceedings for an offence committed after the regulations come into force: s 5(4C) (as so prospectively added). For the meaning of 'prescribed' see PARA 242 note 5 ante. At the date at which this volume states the law, no day had been appointed for the commencement of these provisions and no such regulations had been made. As to the making of regulations see PARA 242 ante.

An offence under the Misuse of Drugs Act 1971 s 5(3) is a 'lifestyle offence' for the purposes of the Proceeds of Crime Act 2002 ss 75, 223: see SENTENCING AND DISPOSITION OF OFFENDERS vol 92 (2010) PARA 393. An offence under the Misuse of Drugs Act 1971 s 5(3) is a 'relevant offence' for the purposes of the Licensing Act 2003 Pt 6 (ss 111-135) (personal licences): see s 113, Sch 4 para 7; and LICENSING AND GAMBLING vol 67 (2008) PARA 117.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

252 Restrictions on possession

NOTE 3--SI 2001/3998 reg 4B (exceptions for gamma-butyrolactone and a, 4-butanediol) added: SI 2009/3136.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(3) THE CONTROL OF DRUGS/(i) Prohibitions and Offences/253. Persons authorised to possess controlled drugs.

253. Persons authorised to possess controlled drugs.

Notwithstanding the general prohibition¹ on the possession of a controlled drug²:

- 242 (1) various of the persons authorised to supply such drugs³ may have in their possession any specified drug for the purpose of acting in their capacity as such a person⁴;
- 243 (2) a person may have in his possession any specified drug for administration for medical, dental or veterinary purposes in accordance with the directions of a practitioner⁵, a supplementary prescriber acting under and in accordance with the terms of a clinical management plan⁶, or an extended formulary nurse prescriber⁷;
- 244 (3) a person who is authorised as a member of a group may, under and in accordance with the terms of his group authority and in compliance with any conditions attached to it, have any specified drug in his possession⁸;
- 245 (4) a person who is authorised by a written authority issued⁹ by the Secretary of State¹⁰ and for the time being in force, may, at the premises specified in that authority and in compliance with any conditions so specified, have in his possession any specified drug¹¹;
- 246 (5) a person who is authorised¹² by the Secretary of State may have in his possession any drug which he may, by virtue of being so authorised, lawfully produce¹³;
- 247 (6) a person who is authorised¹⁴ by the Secretary of State may have in his possession any drug which he may, by virtue of being so authorised, lawfully supply or offer to supply¹⁵;
- 248 (7) any person may have in his possession any specified drug for the purpose of compliance with any of certain¹⁶ provisions¹⁷;
- 249 (8) the master of a foreign ship which is in a port in Great Britain¹⁸ may have in his possession any specified drug so far as necessary for the equipment of the ship¹⁹;
- 250 (9) any person in respect of whom a licence has been granted which is in force under the Wildlife and Countryside Act 1981²⁰ may have in his possession any specified drug for the purposes for which that licence was granted²¹.

Any of the following persons may also have any controlled drug in his possession²²: a constable when acting in the course of his duty as such²³; a person engaged in the business of a carrier when acting in the course of that business²⁴; a person engaged in the business of a postal operator²⁵ when acting in the course of that business²⁶; an officer of customs and excise when acting in the course of his duty as such²⁷; a person engaged in the work of any laboratory to which the drug has been sent for forensic examination when acting in the course of his duty as a person so engaged²⁸; and a person engaged in conveying the drug to a person who may lawfully have that drug in his possession²⁹.

Where any person is authorised by a licence³⁰ of the Secretary of State, for the time being in force, to have in his possession any controlled drug, it is not unlawful³¹ for that person to have in his possession that drug in accordance with the terms of the licence and in compliance with any conditions attached to the licence³².

1 Ie under the Misuse of Drugs Act 1971 s 5(1): see PARA 252 ante.

2 The provisions of the Misuse of Drugs Regulations 2001, SI 2001/3998, reg 10 are without prejudice to the provisions of reg 4(3)(a) (see PARA 252 note 3 ante): reg 10(6). For the meaning of 'controlled drug' see PARA 238 ante.

3 Ie under ibid regs 8, 9: see PARA 251 ante.

4 Ibid reg 10(1). The persons concerned and the drugs specified are:

90 (1) a person specified in reg 8(2)(a)-(k) (see PARA 251 ante) may have in his possession any drug specified in Sch 2 (amended by SI 2003/1432) (Misuse of Drugs Regulations 2001, SI 2001/3998, reg 10(1)(a) (reg 10(1)(a), (b) amended by SI 2005/271));

91 (2) a person specified in the Misuse of Drugs Regulations 2001, SI 2001/3998, reg 9(2)(a)-(i) (see PARA 251 ante) may have in his possession any drug specified in Sch 3, 4 (Sch 4 amended by SI 2003/1432) (Misuse of Drugs Regulations 2001, SI 2001/3998, reg 10(1)(b) (as so amended));

92 (3) a person specified in reg 9(3)(b), (c), (6) (see PARA 251 ante) may have in his possession any drug specified in Sch 3 (reg 10(1)(c));

93 (4) a person specified in reg 9(3)(b), (c) (see PARA 251 ante) may have in his possession any drug specified in Sch 4 Pt I (as so amended) which is contained in a medicinal product (reg 10(1)(d) (reg 10(1)(d), (e) amended by SI 2003/2429));

94 (5) a person specified in the Misuse of Drugs Regulations 2001, SI 2001/3998, reg 9(7) (see PARA 251 ante) may have in his possession any drug specified in that regulation in accordance with the conditions specified in that regulation (reg 10(1)(e) (as so amended)),

except that nothing in these provisions authorises a person specified in reg 8(2)(e), reg 9(3)(c) or reg 9(6), to have in his possession any drug other than such a drug as is mentioned in the head supra specifying him: reg 10(1). For the meaning of 'medicinal product' see PARA 7 ante; definition applied by reg 2(1).

5 For the meaning of 'practitioner' see PARA 243 note 9 ante.

6 For the meanings of 'supplementary prescriber' and 'clinical management plan' see PARA 251 note 15 ante.

7 Misuse of Drugs Regulations 2001, SI 2001/3998, reg 10(2) (amended by SI 2003/2429; SI 2005/271). This provision is subject to certain conditions: see the Misuse of Drugs Regulations 2001, SI 2001/3998, reg 10(2)(a), (b) (reg 10(2)(a) as so amended). For the meaning of 'extended formulary nurse prescriber' see PARA 251 note 22 ante. As to the drugs specified see Schs 2, 3, 4 Pt I (Schs 2, 4 as amended: see note 4 supra).

8 Ibid reg 10(3). As to the specified drugs see Schs 2, 3, 4 Pt I (Schs 2, 4 as amended: see note 4 supra).

9 Ie under and for the purposes of ibid reg 10(4)(a).

10 As to the Secretary of State see PARA 3 note 3 ante.

11 Misuse of Drugs Regulations 2001, SI 2001/3998, reg 10(4)(a). As to the specified drugs see Schs 3, 4 (as amended: see note 4 supra).

12 Ie under ibid reg 9(1)(c): see PARA 251 ante.

13 Ibid reg 10(4)(b).

14 Ie under ibid reg 9(4)(a): see PARA 251 ante.

15 Ibid reg 10(4)(c).

16 As to the provisions see ibid reg 8(6).

17 Ibid reg 10(5)(a). As to the specified drugs see Schs 2, 3, 4 Pt I (Schs 2, 4 as amended: see note 4 supra).

18 For the meaning of 'Great Britain' see PARA 7 note 3 ante.

19 Misuse of Drugs Regulations 2001, SI 2001/3998, reg 10(5)(b). As to the specified drugs see Schs 2, 3, 4 Pt I (Schs 2, 4 as amended: see note 4 supra). For the meaning of 'master' see PARA 251 note 21 ante.

20 Ie the Wildlife and Countryside Act 1981 s 16(1): see ANIMALS vol 2 (2008) PARA 1006.

- 21 Misuse of Drugs Regulations 2001, SI 2001/3998, reg 6(4). As to the specified drugs see Schs 2, 3 (Sch 2 as amended: see note 4 *supra*).
- 22 Ibid reg 6(6).
- 23 Ibid reg 6(7)(a). See POLICE.
- 24 Ibid reg 6(7)(b). See CARRIAGE AND CARRIERS.
- 25 Ie within the meaning of the Postal Services Act 2000: see POST OFFICE.
- 26 Misuse of Drugs Regulations 2001, SI 2001/3998, reg 6(7)(c) (amended by SI 2003/1653).
- 27 Misuse of Drugs Regulations 2001, SI 2001/3998, reg 6(7)(d). See CUSTOMS AND EXCISE.
- 28 Ibid reg 6(7)(e).
- 29 Ibid reg 6(7)(f).
- 30 Ie issued under *ibid* reg 5.
- 31 Ie by virtue of the Misuse of Drugs Act 1971 s 5(1): see PARA 252 *ante*.
- 32 Misuse of Drugs Regulations 2001, SI 2001/3998, reg 5. As to the offence of contravening a term of a licence see the Misuse of Drugs Act 1971 s 18(2); and PARA 260 *post*.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

253 Persons authorised to possess controlled drugs

NOTE 4--SI 2001/3998 Sch 2 amended: see PARA 251 note 16. SI 2001/3998 Sch 3 amended: see PARA 249 NOTE 6. SI 2001/3998 Sch 4 further amended: see PARA 248 NOTE 4. In heads (3), (4), for 'reg 9(3)(b), (c)' read 'reg 9(3)(b)-(d)': reg 10(1)(c), (d) (amended by SI 2007/2154). For 'specified in reg 8(2)(e), reg 9(3)(c)' read 'specified in reg 8(2)(e) or (ea), reg 9(3)(c) or (d)': SI 2001/3998 reg 10(1)(i), (ii) (amended by SI 2007/2154).

TEXT AND NOTE 7--For 'an extended formulary nurse prescriber' read 'a nurse independent prescriber': SI 2001/3998 reg 10(2) (amended by SI 2006/986). For the meaning of 'a nurse independent prescriber' see PARA 251.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(3) THE CONTROL OF DRUGS/(i) Prohibitions and Offences/254. Cultivation of cannabis plants.

254. Cultivation of cannabis plants.

Subject to any regulations¹ for the time being in force, it is not lawful for a person² to cultivate³ any plant of the of the genus *Cannabis*⁴; and to do so in contravention⁵ of this prohibition is⁶ an offence⁷. Where any person is authorised by a licence⁸ of the Secretary of State for the time being in force to cultivate plants of the genus *Cannabis*, it is not unlawful for that person to cultivate any such plant in accordance with the terms of the licence and in compliance with any conditions attached to the licence⁹.

1 The regulations made under the Misuse of Drugs Act 1971 s 7 (see PARA 259 post). As to such regulations see the text to notes 8-9 infra.

2 For the meaning of 'person' see PARA 21 note 7 ante.

3 Cultivation does not require the bestowal of labour or the presence of horticultural equipment. Merely positioning a plant in the window to secure the light necessary for growth, together with the objective of growing the plant, is sufficient: *Tudhope v Robertson* 1980 SLT 60.

4 Misuse of Drugs Act 1971 s 6(1). See also CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARA 774.

5 For the meaning of 'contravention' see PARA 249 note 9 ante.

6 The subject to the Misuse of Drugs Act 1971 s 28 (defence of lack of knowledge): see PARA 262 post.

7 Ibid s 6(2). The penalty on summary conviction is imprisonment for a term not exceeding six months or a fine not exceeding the prescribed sum or both, and on conviction on indictment is imprisonment for a term not exceeding 14 years or a fine or both: s 25(1), (2), Sch 4 (amended by virtue of the Magistrates' Courts Act 1980 ss 31(1)-(3), 32(2)). As to the prescribed sum see PARA 32 note 3 ante. It is not a defence to such an offence that cultivation was out of necessity and for personal use to alleviate pain: *R v Quayle* [2005] EWCA Crim 1415, (2005) Times, 22 June, [2005] All ER (D) 447 (May).

As to incitement to commit an offence see PARA 260 post. As to powers of entry, search and seizure see PARAS 279-280 post. As to the prosecution of offences in the magistrates' court see PARA 282 post. As to the powers of a court to order forfeiture of anything shown to relate to an offence see PARA 283 post. As to the powers of the Secretary of State to exclude the application of the Misuse of Drugs Act 1971 s 6(2) see s 22; and PARA 243 ante. As to the Secretary of State see PARA 3 note 3 ante.

8 The issued under the Misuse of Drugs Regulations 2001, SI 2001/3998, reg 12.

9 Ibid reg 12. As to the offence of contravening a term of a licence see the Misuse of Drugs Act 1971 s 18(2); and PARA 260 post.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(3) THE CONTROL OF DRUGS/(i) Prohibitions and Offences/255. Offences by occupiers of premises.

255. Offences by occupiers of premises.

An occupier or person¹ concerned in the management of premises² commits an offence if he knowingly permits or suffers any of the following activities to take place on the premises³: (1) producing⁴ or attempting to produce a controlled drug⁵ in contravention⁶ of the Misuse of Drugs Act 1971⁷; (2) supplying⁸ or attempting to supply, or offering to supply, a controlled drug to another in contravention⁹ of the Act¹⁰; (3) preparing opium for smoking¹¹; or (4) smoking cannabis¹², cannabis resin¹³ or prepared opium¹⁴. These provisions do not have effect in relation to the smoking of cannabis or cannabis resin for the purposes of research on any premises for the time being approved¹⁵ for the purpose by the Secretary of State¹⁶.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 Lawful possession of the premises is not required: *R v Josephs, R v Christie* (1977) 65 Cr App Rep 253, CA (trespassers in fact concerned in management).

3 Misuse of Drugs Act 1971 s 8. In respect of a Class A drug or a Class B drug (see PARAS 238-240 ante), the penalty for an offence under s 8 on summary conviction is imprisonment for a term not exceeding six months or a fine not exceeding the prescribed sum or both, and on conviction on indictment is imprisonment for a term not exceeding 14 years or a fine or both; and in respect of a Class C drug (see PARAS 238, 241 ante), the penalty on summary conviction is imprisonment for a term not exceeding three months or a fine not exceeding £2,500 or both, and on conviction on indictment is imprisonment for a term not exceeding 14 years or a fine or both: s 25(1), (2), Sch 4 (amended by the Criminal Justice and Public Order Act 1994 s 157(2), (4), Sch 8 Pt II; and the Criminal Justice Act 2003 s 284, Sch 28 para 1). As to the prescribed sum see PARA 32 note 3 ante. For cases relevant to the Misuse of Drugs Act 1971 s 8 see further CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARA 777. As to incitement to commit an offence see PARA 260 post. As to powers of entry, search and seizure see PARAS 279-280 post. As to the prosecution of offences in the magistrates' court see PARA 282 post. As to the powers of a court to order forfeiture of anything shown to relate to an offence see PARA 283 post. An offence under the Misuse of Drugs Act 1971 s 8 is a 'relevant offence' for the purposes of the Licensing Act 2003 Pt 6 (ss 111-135) (personal licences): see s 113, Sch 4 para 7; and LICENSING AND GAMBLING vol 67 (2008) PARA 117. An offence under the Misuse of Drugs Act 1971 s 4(2), (3) is a 'lifestyle offence' for the purposes of the Proceeds of Crime Act 2002 ss 75, 223: see SENTENCING AND DISPOSITION OF OFFENDERS vol 92 (2010) PARA 393.

4 For the meaning of 'produce' see PARA 249 note 3 ante.

5 For the meaning of 'controlled drug' see PARA 238 ante.

6 I.e. contravention of the Misuse of Drugs Act 1971 s 4(1): see PARA 249 ante. For the meaning of 'contravention' see PARA 249 note 9 ante.

7 Ibid s 8(a).

8 As to the meaning 'supplying' see PARA 249 note 5 ante.

9 I.e. contravention of the Misuse of Drugs Act 1971 s 4(1): see PARA 249 ante.

10 Ibid s 8(b).

11 Ibid s 8(c). As to offences relating to opium see PARA 257 post.

12 For the meaning of 'cannabis' see PARA 241 note 4 ante.

13 For the meaning of 'cannabis resin' see PARA 241 note 5 ante.

14 Misuse of Drugs Act 1971 s 8(d). 'Prepared opium' means opium prepared for smoking and includes dross and any other residues remaining after opium has been smoked: s 37(1). As to restrictions on the cultivation of cannabis plants see PARA 254 ante.

As from a day to be appointed, s 8(d) is substituted so as to refer to administering or using a controlled drug which is unlawfully in any person's possession at or immediately before the time when it is administered or used: s 8(d) (prospectively substituted by the Criminal Justice and Police Act 2001 ss 38, 138(2)). At the date at which this volume states the law, no such day had been appointed.

15 le under the Misuse of Drugs Regulations 2001, SI 2001/3998, reg 13.

16 Ibid reg 13. As to the Secretary of State see PARA 3 note 3 ante.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(3) THE CONTROL OF DRUGS/(i) Prohibitions and Offences/256. Closure of premises.

256. Closure of premises.

If a police officer not below the rank of superintendent has reasonable grounds for believing that premises¹ have been used in connection with the unlawful use, production or supply of a Class A controlled drug², and that the use of the premises is associated with the occurrence of disorder or serious nuisance to members of the public³, he may authorise the issue of a closure notice in respect of premises⁴. If a closure notice has been issued, a constable must apply to a magistrates' court for the making of a closure order⁵. A closure order is an order that the premises in respect of which the order is made are to be closed to all persons for such period, not exceeding three months, as the court decides⁶.

1 'Premises' includes any land or other place (whether enclosed or not) and any outbuildings which are, or are used as, part of the premises: Anti-Social Behaviour Act 2003 s 11(3).

2 Ibid s 1(1)(a). For the meanings of 'controlled drug' and 'Class A drug' see PARA 238 ante; definitions applied by s 11(2).

3 Ibid s 1(1)(b).

4 See ibid s 1(2).

5 See ibid s 2(1).

6 Ibid s 2(4). As to closure orders generally see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARA 782.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

256 Closure of premises

NOTES--Certain functions under provisions mentioned in this paragraph are 'relevant functions' for the purposes of the Regulatory Enforcement and Sanctions Act 2008 s 4, Sch 3, see LOCAL GOVERNMENT vol 69 (2009) PARA 733.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(3) THE CONTROL OF DRUGS/(i) Prohibitions and Offences/257. Offences relating to opium.

257. Offences relating to opium.

It is¹ an offence² for a person to smoke or otherwise use prepared opium³ or to frequent a place used for the purpose of opium smoking⁴. It is also an offence for a person to have in his possession⁵ any pipes or other utensils made or adapted for use in connection with the smoking of opium, being pipes or utensils which have been used by him or with his knowledge and permission in that connection or which he intends to use or permit others to use in that connection⁶, or any utensils which have been used by him or with his knowledge and permission in connection with the preparation of opium for smoking⁷.

1 Ie subject to the Misuse of Drugs Act 1971 s 28 (defence of lack of knowledge): see PARA 262 post.

2 The penalty for any offence under ibid s 9 on summary conviction is imprisonment for a term not exceeding six months or a fine not exceeding the prescribed sum or both, and on conviction on indictment is imprisonment for a term not exceeding 14 years or a fine or both: s 25(1), (2), Sch 4 (amended by virtue of the Magistrates' Courts Act 1980 ss 31(1)-(3), 32(2)). As to the prescribed sum see PARA 32 note 3 ante. As to these offences see also CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARA 775. As to incitement to commit an offence see PARA 260 post. As to powers of entry, search and seizure see PARAS 279-280 post. As to the prosecution of offences in the magistrates' court see PARA 282 post. As to the powers of a court to order forfeiture of anything shown to relate to an offence see PARA 283 post.

3 Misuse of Drugs Act 1971 s 9(a). For the meaning of 'prepared opium' see PARA 255 note 14 ante.

4 Ibid s 9(b).

5 As to the meaning of 'possession' see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARA 771.

6 Misuse of Drugs Act 1971 s 9(c)(i).

7 Ibid s 9(c)(ii).

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(3) THE CONTROL OF DRUGS/(i) Prohibitions and Offences/258. Supply of articles for administration of controlled drugs.

258. Supply of articles for administration of controlled drugs.

It is an offence for a person to supply¹ or offer to supply any article² which may be used or adapted to be used, whether by itself or in combination with another article or other articles, in the administration by any person of a controlled drug³ to himself⁴ or another, believing that the article, or the article as adapted, is to be so used in circumstances where the administration⁵ is unlawful⁶. It is also an offence for a person to supply or offer to supply any article which may be used to prepare a controlled drug for administration by any person to himself or another believing that the article is to be so used in circumstances where the administration is unlawful⁷.

Notwithstanding these provisions, any of the following persons may, when acting in their capacity as such, supply or offer to supply specified articles⁸. The persons concerned are a practitioner⁹, a pharmacist¹⁰, a person employed or engaged in the lawful provision of drug treatment services¹¹, and a supplementary prescriber¹² acting under and in accordance with the terms of a clinical management plan¹³.

1 As to the meaning 'supplying' see PARA 249 note 5 ante.

2 It is not an offence to supply a hypodermic syringe, or any part of one: Misuse of Drugs Act 1971 s 9A(2) (s 9A added by the Drug Trafficking Offences Act 1986 s 34(1)).

3 For the meaning of 'controlled drug' see PARA 238 ante.

4 References to administration by any person of a controlled drug to himself include a reference to his administering it to himself with the assistance of another: Misuse of Drugs Act 1971 s 9A(5) (as added: see note 2 supra).

5 Any administration of a controlled drug is unlawful except: (1) the administration by any person of a controlled drug to another in circumstances where the administration of the drug is not unlawful under ibid s 4(1) (see PARA 249 ante) (s 9A(4)(a) (as added: see note 2 supra)); or (2) the administration by any person of a controlled drug to himself in circumstances where having the controlled drug in his possession is not unlawful under s 5(1) (see PARA 252 ante) (s 9A(4)(b) (as so added)).

6 Ibid s 9A(1) (as added: see note 2 supra). The penalty for an offence under s 9A (as added) on summary conviction is imprisonment for a term not exceeding six months or a fine not exceeding level 5 on the standard scale or both: s 25(1), (2), Sch 4 (amended by the Drug Trafficking Offences Act 1986 s 34(2)). As to the standard scale see PARA 6 note 22 ante. As to offences under the Misuse of Drugs Act 1971 s 9A (as added) see further CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARA 776. As to incitement to commit an offence see PARA 260 post. As to powers of entry, search and seizure see PARAS 279-280 post. As to the prosecution of offences in the magistrates' court see PARA 282 post. As to the powers of a court to order forfeiture of anything shown to relate to an offence see PARA 283 post.

7 Misuse of Drugs Act 1971 s 9A(3) (as added: see note 2 supra). See also note 6 supra.

8 Misuse of Drugs Regulations 2001, SI 2001/3998, reg 6A(1) (reg 6A added by SI 2003/1653). The specified articles are: a swab; utensils for the preparation of a controlled drug; citric acid; a filter; ampoules of water for injection, but only when supplied or offered for supply in accordance with the Medicines Act 1968 and of any instrument which is in force thereunder: Misuse of Drugs Regulations 2001, SI 2001/3998, reg 6A(1)(a)-(e) (as so added).

9 Ibid reg 6A(2)(a) (as added: see note 8 supra). For the meaning of 'practitioner' see PARA 243 note 9 ante.

10 Ibid reg 6A(2)(b) (as added: see note 8 supra). For the meaning of 'pharmacist' see PARA 46 note 10 ante.

11 Ibid reg 6A(2)(c) (as added: see note 8 supra).

12 For the meaning of 'supplementary prescriber' see PARA 251 note 15 ante.

13 Misuse of Drugs Regulations 2001, SI 2001/3998, reg 6A(2)(d) (reg 6A as added (see note 8 supra); and reg 6A(2)(d) added by SI 2005/271). For the meaning of 'clinical management plan' see PARA 251 note 15 ante.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

258 Supply of articles for administration of controlled drugs

NOTE 8--Ascorbic acid added to the list of specified articles: see SI 2001/3998 reg 6A(1) (f) (added by SI 2005/2864).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(3) THE CONTROL OF DRUGS/(i) Prohibitions and Offences/259. Authorisation of activities otherwise unlawful.

259. Authorisation of activities otherwise unlawful.

The Secretary of State¹ may by regulations² except such controlled drugs³ specified in the regulations from any of the restrictions imposed by the Misuse of Drugs Act 1971 on their importation, exportation⁴, production, supply⁵ or possession⁶, and make such other provision as he thinks fit for the purpose of making it lawful for persons⁷ to produce, supply or possess any controlled drug or to cultivate cannabis⁸. In particular, such regulations may provide for the doing⁹ of a thing to be lawful if done under and in accordance with the terms of a licence¹⁰ or other authority issued by the Secretary of State and in compliance with any conditions attached to such licence or authority¹¹ or prescribed in the regulations¹².

The Secretary of State must so exercise his power to make regulations as to secure that it is not unlawful¹³ for a doctor, dentist, veterinary practitioner or veterinary surgeon¹⁴ acting in his capacity as such to prescribe, administer, manufacture, compound or supply a controlled drug, or for a pharmacist¹⁵ or person lawfully conducting a retail pharmacy business¹⁶ while acting in his capacity as such to manufacture, compound or supply a controlled drug¹⁷, and that it is not unlawful¹⁸ for any of those persons to have a controlled drug in his possession for the purpose of acting in that capacity¹⁹.

The Secretary of State has additional powers if in the case of any controlled drug he is of the opinion that it is in the public interest for its production, supply and possession to be either wholly unlawful or unlawful except for purposes of research or other special purposes²⁰, or for it to be unlawful for practitioners²¹, pharmacists and persons lawfully conducting retail pharmacy businesses to do in relation to that drug any of the things mentioned above²² except under a licence or other authority issued by the Secretary of State²³. In these circumstances he may by order²⁴ designate that drug as a drug to which this provision²⁵ applies²⁶.

1 As to the Secretary of State see PARA 3 note 3 ante.

2 As to the making of regulations see PARA 242 ante. As to the regulations that have been made see the Misuse of Drugs Regulations 2001, SI 2001/3998 (amended by SI 2003/1432; SI 2003/1653; SI 2003/2429; SI 2004/1031; SI 2004/1771; SI 2005/271).

3 For the meaning of 'controlled drug' see PARA 238 ante.

4 As to restrictions on the importation and exportation of controlled drugs see the Misuse of Drugs Act 1971 s 3(1); and PARA 248 ante.

5 As to restrictions on the production and supply of controlled drugs see *ibid* s 4(1); and PARA 249 ante. For the meaning of 'produce' see PARA 249 note 3 ante. As to the meaning 'supplying' see PARA 249 note 5 ante.

6 *Ibid* s 7(1)(a). As to restrictions on the possession of controlled drugs see s 5(1); and PARA 252 ante. The exceptions specified are general and are not restricted to possession for medical purposes: *R v Hunt* [1986] QB 125, [1986] 1 All ER 184, CA (conviction quashed on appeal: see [1987] AC 352, [1987] 1 All ER 1, HL).

7 For the meaning of 'person' see PARA 21 note 7 ante.

8 Misuse of Drugs Act 1971 s 7(1)(b). These acts would otherwise be unlawful under ss 4(1), 5(1), 6(1). As to restrictions on the cultivation of cannabis see s 6(1); and PARA 254 ante. For the meaning of 'cannabis' see PARA 241 note 4 ante.

9 References to a person's 'doing' things include references to his having things in his possession: *ibid* s 7(8). As to the meaning of 'possession' see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARA 771.

10 It is an offence to contravene a condition or other term of a licence or other authority granted under the Misuse of Drugs Act 1971: see s 18(2); and PARA 260 post. As to licences see PARA 244 ante.

11 Ibid s 7(2)(a). As to the power of the Secretary of State to modify or revoke a licence or authority see PARA 244 ante.

12 Ibid s 7(2)(b).

13 Ie under ibid s 4(1): see PARA 249 ante.

14 For the meanings of 'doctor', 'dentist', 'veterinary practitioner' and 'veterinary surgeon' see PARA 243 note 9 ante.

15 For the meaning of 'pharmacist' see PARA 46 note 10 ante.

16 For the meaning of 'person lawfully conducting a retail pharmacy business' see PARA 250 note 6 ante.

17 Misuse of Drugs Act 1971 s 7(3)(a).

18 Ie under ibid s 5(1): see PARA 252 ante.

19 Ibid s 7(3)(b).

20 Ibid s 7(4)(a).

21 For the meaning of 'practitioner' see PARA 243 note 9 ante.

22 Ie any of the things mentioned in the Misuse of Drugs Act 1971 s 7(3): see the text to notes 13-19 supra.

23 Ibid s 7(4)(b).

24 The power to make orders under ibid s 7(4) is exercisable by statutory instrument, which is subject to annulment in pursuance of a resolution of either House of Parliament: s 7(6). Any such order may be varied or revoked by a subsequent order: s 7(5). The Secretary of State may not make such an order except after consultation with or on the recommendation of the Advisory Council: s 7(7). As to the annulment of statutory instruments see STATUTES vol 44(1) (Reissue) PARA 1516. For the meaning of 'the Advisory Council' see PARA 246 note 1 ante. As to the order that has been made see the Misuse of Drugs (Designation) Order 2001, SI 2001/3997 (amended by SI 2005/1652).

25 Ie the Misuse of Drugs Act 1971 s 7(4).

26 See ibid s 7(4). Where such an order is in force designating any drug, s 7(3) (see the text and notes 13-19 supra) does not apply to that drug: see s 7(4).

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

259 Authorisation of activities otherwise unlawful

NOTE 2--SI 2001/3998 further amended: see PARA 243 NOTE 2.

NOTE 24--SI 2001/3997 further amended: SI 2009/3135, SI 2010/1143.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(3) THE CONTROL OF DRUGS/(i) Prohibitions and Offences/260. Miscellaneous offences.

260. Miscellaneous offences.

It is an offence for a person¹: (1) to contravene² any regulations, other than the addiction regulations³, made under the Misuse of Drugs Act 1971⁴; (2) to contravene a condition or other term of a licence⁵ permitting the importation or exportation of a controlled drug⁶ or of a licence or other authority issued under regulations made under the Act, other than a licence⁷ issued under the addiction regulations⁸; (3) to give any information⁹ which he knows to be false in a material particular or recklessly to give any information which is false in a material particular¹⁰; (4) for the purpose of obtaining, whether for himself or another, the issue or renewal of a licence or other authority under the Act or under any regulations made under it, to make any statement or give any information which he knows to be false in a material particular or recklessly to give any information which is false in a material particular¹¹, or for that purpose to produce or otherwise make use of any book, record or other document which to his knowledge contains any statement or information which he knows to be false in a material particular¹²; (5) to incite another to commit an offence under the Act¹³; (6) in the United Kingdom¹⁴ to assist in or induce the commission in any place outside the United Kingdom of an offence punishable under the provisions of a corresponding law¹⁵ in force in that place¹⁶.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 For the meaning of 'contravene' see PARA 249 note 9 ante.

3 I.e. regulations made in pursuance of the Misuse of Drugs Act 1971 s 10(2)(h) or (i): see PARAS 263, 271 post. As to the consequences of contravening such regulations see PARA 273 post.

4 Ibid s 18(1). A person committing an offence under s 18 is liable on summary conviction to imprisonment for a term not exceeding six months or to a fine not exceeding the prescribed sum or to both, or on conviction on indictment to imprisonment for a term not exceeding two years or to a fine or to both: s 25(1), (2), Sch 4 (amended by virtue of the Magistrates' Courts Act 1980 s 32(2)). As to the prescribed sum see PARA 32 note 3 ante. As to powers of entry, search and seizure see PARAS 279-280 post. As to the prosecution of offences in the magistrates' court see PARA 282 post. As to the powers of a court to order forfeiture of anything shown to relate to an offence see PARA 283 post.

5 I.e. a licence issued under the Misuse of Drugs Act 1971 s 3: see PARA 248 ante.

6 For the meaning of 'controlled drug' see PARA 238 ante.

7 I.e. a licence issued under regulations made in pursuance of the Misuse of Drugs Act 1971 s 10(2)(i); and PARA 271 post.

8 Ibid s 18(2). For the penalties see note 4 supra.

9 I.e. in purported compliance with any obligation to give information to which he is subject under or by virtue of regulations made under the Misuse of Drugs Act 1971: s 18(3).

10 Ibid s 18(3). For the penalties see note 4 supra.

11 Ibid s 18(4)(a). For the penalties see note 4 supra.

12 Ibid s 18(4)(b). For the penalties see note 4 supra.

13 Ibid s 19 (amended by the Criminal Attempts Act 1981 s 10, Schedule Pt I). Such an offence is punishable in the same manner as the substantive offence (i.e. the offence to which the incitement was directed): Misuse of Drugs Act 1971 s 25(3) (amended by the Criminal Attempts Act 1981 Schedule Pt I). As to incitement see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(1) (2006 Reissue) PARA 65. For the power of the court to impose a

travel banning order on an individual convicted of an offence under the Misuse of Drugs Act 1971 s 19 see the Criminal Justice and Police Act 2001 ss 33-37; and SENTENCING AND DISPOSITION OF OFFENDERS vol 92 (2010) PARAS 371-374.

14 For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

15 'Corresponding law' means a law stated in a certificate purporting to be issued by or on behalf of the government of a country outside the United Kingdom to be a law providing for the control and regulation in that country of the production, supply, use, export and import of drugs and other substances in accordance with the provisions of the Single Convention on Narcotic Drugs (New York, 30 March to 1 August 1961; TS 34 (1965) Cmnd 2631), amended by Protocol (Geneva, 25 March to 31 December 1972; TS 23 (1979); Cmnd 7466) or a law providing for the control and regulation in that country of the production, supply, use, export and import of dangerous or otherwise harmful drugs in pursuance of any treaty, convention or other agreement or arrangement to which the government of that country and Her Majesty's government in the United Kingdom are for the time being parties: Misuse of Drugs Act 1971 ss 36(1), 37(1). A statement in any such certificate to the effect that any facts constitute an offence against the law mentioned in the certificate is evidence of the matters stated: s 36(2).

16 Ibid s 20. A person guilty of an offence under s 20 is liable on summary conviction to imprisonment for a term not exceeding six months or to a fine not exceeding the prescribed sum or to both, or on conviction on indictment to imprisonment for a term not exceeding 14 years or to a fine or to both: Sch 4 (as amended: see note 4 supra). The defendant may assist without taking part in the act constituting the offence under the corresponding law. The offence is not one of strict liability, and the word 'assist' should be given its ordinary English usage: *R v Vickers* [1975] 2 All ER 945, [1975] 1 WLR 811, CA; *R v Evans* (1976) 64 Cr App Rep 237, CA. As to this offence and cases relating to it see further CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARA 779. For the power of the court to impose a travel banning order on an individual convicted of an offence under the Misuse of Drugs Act 1971 s 20 see the Criminal Justice and Police Act 2001 ss 33-37; and SENTENCING AND DISPOSITION OF OFFENDERS vol 92 (2010) PARAS 371-374. An offence under the Misuse of Drugs Act 1971 s 20 is a 'lifestyle offence' for the purposes of the Proceeds of Crime Act 2002 ss 75, 223: see SENTENCING AND DISPOSITION OF OFFENDERS vol 92 (2010) PARA 393.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(3) THE CONTROL OF DRUGS/(i) Prohibitions and Offences/261. Offences by bodies corporate.

261. Offences by bodies corporate.

Where any offence under the Misuse of Drugs Act 1971 or Part II of the Criminal Justice (International Co-operation) Act 1990¹ committed by a body corporate is proved to have been committed with the consent or connivance of, or to be attributable to any neglect on the part of, any director, manager, secretary or other similar officer of the body corporate, or any person purporting to act in such capacity, he as well as the body corporate is guilty of that offence and is liable to be proceeded against accordingly².

¹ I.e. the Criminal Justice (International Co-operation) Act 1990 Pt II (ss 12-24): see CRIMINAL LAW, EVIDENCE AND PROCEDURE VOL 11(2) (2006 Reissue) PARAS 772-773, 780.

² Misuse of Drugs Act 1971 s 21 (amended by the Criminal Justice (International Co-operation) Act 1990 s 23 (1), (3); and the Proceeds of Crime Act 2002 s 457, Sch 12). As to bodies corporate see COMPANIES; CORPORATIONS.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(3) THE CONTROL OF DRUGS/(i) Prohibitions and Offences/262. Defence of lack of knowledge.

262. Defence of lack of knowledge.

In proceedings for certain offences¹ it is a defence for the accused to prove² that he neither knew of nor suspected nor had reason³ to suspect the existence of some fact alleged by the prosecution which the prosecution must prove if he is to be convicted⁴. The offences in question are: (1) unlawfully producing, supplying or offering to supply a controlled drug⁵; (2) being concerned in such an activity⁶; (3) being in unlawful possession of a controlled drug⁷; (4) being in possession of a controlled drug with intent unlawfully to supply it to another⁸; (5) unlawfully cultivating a cannabis plant⁹; and (6) any prohibited activity relating to opium¹⁰.

Where in any such proceedings it is necessary, if the accused is to be convicted of the offence charged, for the prosecution to prove that some substance or product involved was the controlled drug alleged, and this is proved, the accused must not be acquitted by reason only of proving that he neither knew nor suspected nor had reason to suspect that it was the particular controlled drug alleged¹¹; but he must be acquitted if he proves that he neither believed nor suspected nor had reason to suspect that it was a controlled drug¹², or if he proves that he believed it to be a controlled drug, or a controlled drug of a description, such that he would not have been committing any of those offences if it had in fact been that controlled drug or a controlled drug of that description¹³.

1 See the Misuse of Drugs Act 1971 s 28(1); and text to notes 5-10 *infra*. By reason of the Criminal Justice (International Co-operation) Act 1990 s 19(5), the defence in the Misuse of Drugs Act 1971 s 28 also applies to the offence under the Criminal Justice (International Co-operation) Act 1990 s 19 of using a ship for illicit drug trafficking: see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARA 780.

2 As to the standard of proof on the accused see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(3) (2006 Reissue) PARA 1372.

3 The test with regard to this element of the defence is objective: *R v Young* [1984] 2 All ER 164, [1984] 1 WLR 654, C-MAC.

4 Misuse of Drugs Act 1971 s 28(2). Any other defence available to the accused is not prejudiced by anything in s 28: see s 28(4). Section 28 does not apply to the offence of conspiracy: *R v McGowan* [1990] Crim LR 399, CA.

5 Ie an offence under the Misuse of Drugs Act 1971 s 4(2)(a), (3)(a): see PARA 249 *ante*. For the meaning of 'controlled drug' see PARA 238 *ante*.

6 Ie an offence under *ibid* s 4(2)(b), (3)(b), (c): see PARA 249 *ante*.

7 Ie an offence under *ibid* s 5(2): see PARA 252 *ante*.

8 Ie an offence under *ibid* s 5(3): see PARA 252 *ante*.

9 Ie an offence under *ibid* s 6(2): see PARA 254 *ante*.

10 *Ibid* s 28(1). The offence referred to in head (6) in the text is an offence under s 9: see PARA 257 *ante*.

11 *Ibid* s 28(3)(a).

12 *Ibid* s 28(3)(b)(i). See *R v McNamara* (1988) 152 JP 390, CA; and CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARA 770.

13 Misuse of Drugs Act 1971 s 28(3)(b)(ii).

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(3) THE CONTROL OF DRUGS/(ii) Prevention of Misuse of Controlled Drugs/263. Regulations for preventing misuse.

(ii) Prevention of Misuse of Controlled Drugs

263. Regulations for preventing misuse.

The Secretary of State¹ has power to make regulations² making such provision as appears to him necessary or expedient for preventing the misuse³ of controlled drugs⁴. Such regulations may in particular make provision:

- 251 (1) for requiring precautions to be taken for the safe custody of controlled drugs⁵;
- 252 (2) for requiring the documentation of transactions involving controlled drugs and the furnishing of copies of documents relating to such transactions to the prescribed authority⁶;
- 253 (3) for requiring the keeping of records and the furnishing of information⁷;
- 254 (4) for providing for the inspection of precautions taken or records kept⁸;
- 255 (5) as to packaging and labelling⁹;
- 256 (6) for regulating transport and providing for the destruction or disposal of drugs no longer required¹⁰;
- 257 (7) for regulating the issue and supply of prescriptions, and requiring persons issuing prescriptions to furnish information relating thereto¹¹;
- 258 (8) for requiring a doctor¹² attending a person considered or suspected to be an addict to furnish particulars¹³; and
- 259 (9) for prohibiting a doctor from administering and supplying¹⁴ controlled drugs to addicts and from authorising the administration and supply of, and prescribing, such drugs for addicts except under licence¹⁵.

1 As to the Secretary of State see PARA 3 note 3 ante.

2 As to the making of regulations see PARA 242 ante.

3 As to references to misusing a drug see PARA 246 note 5 ante.

4 Misuse of Drugs Act 1971 s 10(1). For the meaning of 'controlled drug' see PARA 238 ante. The following regulations have been made: the Misuse of Drugs (Safe Custody) Regulations 1973, SI 1973/798 (amended by SI 1974/1449, SI 1975/294, SI 1986/2332, SI 1999/1043, SI 2001/1149); the Misuse of Drugs (Supply to Addicts) Regulations 1997, SI 1997/1001; and the Misuse of Drugs Regulations 2001, SI 2001/3998 (amended by SI 2003/1432, SI 2003/1653, SI 2003/2429, SI 2004/1031, SI 2004/1771, SI 2005/271).

5 Misuse of Drugs Act 1971 s 10(2)(a). See PARA 264 post. See also s 11; and PARA 265 post.

6 Ibid s 10(2)(b). See PARA 266 post. 'Prescribed' means prescribed by regulations made by the Secretary of State under the Misuse of Drugs Act 1971: s 37(1).

7 Ibid s 10(2)(c). See PARA 267 post. See also s 17; and PARA 268 post.

8 Ibid s 10(2)(d). See PARA 267 post.

9 Ibid s 10(2)(e). See PARA 269 post.

10 Ibid s 10(2)(f). See PARA 264 post.

11 Ibid s 10(2)(g). See PARA 270 post.

12 For the meaning of 'doctor' see PARA 243 note 9 ante.

13 Misuse of Drugs Act 1971 s 10(2)(h). See PARA 271 post.

14 As to the meaning 'supplying' see PARA 249 note 5 ante.

15 Misuse of Drugs Act 1971 s 10(2)(i). See PARA 271 post.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

263 Regulations for preventing misuse

NOTE 4--SI 1973/798 further amended: SI 2007/2154. SI 2001/3998 further amended: see PARA 243 NOTE 2.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(3) THE CONTROL OF DRUGS/(ii) Prevention of Misuse of Controlled Drugs/264. Custody of controlled drugs.

264. Custody of controlled drugs.

The occupier and every person concerned in the management of certain premises¹ must ensure that all controlled drugs² on the premises are, so far as circumstances permit, kept in a locked safe, cabinet or room which is so constructed and maintained as to prevent unauthorised access to the drugs³. Structural requirements are prescribed for safes, cabinets and rooms used for keeping drugs in accordance with this rule⁴. Where any controlled drug is kept otherwise than in a locked safe, cabinet or room which is so constructed and maintained as to prevent unauthorised access to the drug, any person having possession of the drug must ensure that, so far as circumstances permit, it is kept in a locked receptacle⁵ which can be opened only by him or by a person authorised by him⁶.

Provision is made for the destruction of controlled drugs in certain circumstances in accordance with prescribed conditions⁷.

1 le any premises occupied by a retail dealer for the purposes of his business, or any nursing home or mental nursing home: Misuse of Drugs (Safe Custody) Regulations 1973, SI 1973/798, reg 3(1). The regulations refer to such homes within the meaning of the Public Health Act 1936 and the Mental Health Act 1959, but these Acts have been repealed: see now the Care Standards Act 2000; and SOCIAL SERVICES AND COMMUNITY CARE. 'Retail dealer' means a person lawfully conducting a retail pharmacy business or a pharmacist engaged in supplying drugs to the public at a health centre: Misuse of Drugs (Safe Custody) Regulations 1973, SI 1973/798, reg 2(1). For the meaning of 'retail pharmacy business' see PARA 51 note 3 ante; for the meaning of 'pharmacist' see PARA 46 note 10 ante; and for the meaning of 'health centre' see PARA 51 note 9 ante (definitions applied by reg 2(1)).

2 le other than those specified in *ibid* Sch 1 (substituted by SI 1986/2332; and amended by SI 1999/1403; SI 2005/1653). For the meaning of 'controlled drug' see PARA 238 ante.

3 Misuse of Drugs (Safe Custody) Regulations 1973, SI 1973/798, reg 3(2). These requirements do not apply in certain cases where the controlled drug is for the time being under the direct personal supervision of: (1) in the case of premises occupied by a retail dealer, a pharmacist who is not prohibited from handling the drugs under the Misuse of Drugs Act 1971 s 12(2) (see PARA 272 post); or (2) in the other cases, the person in charge of the premises or a designated member of that person's staff: Misuse of Drugs (Safe Custody) Regulations 1973, SI 1973/798, reg 3(4).

4 *Ibid* reg 3(3), Sch 2 (amended by SI 1975/294). An exception to these requirements is made in the case of a person lawfully conducting a retail pharmacy business who holds a current certificate issued by the chief officer of police for the police area in which the premises are situated: see the Misuse of Drugs (Safe Custody) Regulations 1973, SI 1973/798, regs 3(4), 4(1). The chief officer of police, on application by the occupier of premises, and after inspection of the premises and particularly of the room, cabinet or safe in which the controlled drugs are to be stored, may grant such a certificate with or without conditions: reg 4(2), (3). The certificate remains in force for one year: reg 4(6). Further inspection may be carried out while the certificate is in force, and the certificate may be cancelled for breach of a condition, change of circumstances, or refusal to admit a police officer to make an inspection: reg 4(4), (5).

5 In *Dhulipala Kameswara Rao v Wyles* [1949] 2 All ER 685, DC, it was held that a motor car was not a receptacle for the purpose of corresponding earlier regulations.

6 Misuse of Drugs (Safe Custody) Regulations 1973, SI 1973/798, reg 5(1). This requirement applies to any person other than: (1) a person to whom the drug has been supplied by or on the prescription of a practitioner for his own treatment or that of another person or an animal (reg 5(2)(a)); (2) a person engaged in the business of a carrier when acting in the course of that business (reg 5(2)(b)); (3) a person engaged in the business of a postal operator (within the meaning of the Postal Services Act 2000: see POST OFFICE) when acting in the course of that business (reg 5(2)(c) (amended by SI 2001/1149)). For the meaning of 'practitioner' see PARA 243 note 9 ante. As to carriers generally see CARRIAGE AND CARRIERS.

- 7 See the Misuse of Drugs Regulations 2001, SI 2001/3998, reg 27.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

264 Custody of controlled drugs

NOTE 1--For 'any nursing home or mental nursing home' read 'a care home': SI 1973/798 reg 3(1) (amended by SI 2007/2154).

NOTE 2--1973/798 Sch 1 further amended: SI 2007/2154.

NOTE 7--SI 2001/3998 reg 27 amended: SI 2007/2154.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(3) THE CONTROL OF DRUGS/(ii) Prevention of Misuse of Controlled Drugs/265. Notices directing special precautions for safe custody.

265. Notices directing special precautions for safe custody.

The Secretary of State¹, by written² notice served³ on the occupier of any premises on which controlled drugs⁴ are or are proposed to be kept, may give directions as to the taking of precautions or further precautions for the safe custody of any controlled drugs of a description specified in the notice which are kept there⁵. It is an offence to contravene⁶ such a direction⁷.

1 As to the Secretary of State see PARA 3 note 3 ante.

2 'Writing' includes typing, printing, lithography, photography and other modes of representing or reproducing words in a visible form; and expressions referring to writing are to be construed accordingly: Interpretation Act 1978 s 5, Sch 1.

3 As to the service of notices see PARA 245 ante.

4 For the meaning of 'controlled drug' see PARA 238 ante.

5 Misuse of Drugs Act 1971 s 11(1).

6 For the meaning of 'contravene' see PARA 249 note 9 ante.

7 Misuse of Drugs Act 1971 s 11(2). The penalty on summary conviction is imprisonment for a term not exceeding six months or a fine not exceeding the prescribed sum or both, and on conviction on indictment is imprisonment for a term not exceeding two years or a fine or both: s 25(1), (2), Sch 4 (amended by virtue of the Magistrates' Courts Act 1980 s 32(2)). As to the prescribed sum see PARA 32 note 3 ante.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(3) THE CONTROL OF DRUGS/(ii) Prevention of Misuse of Controlled Drugs/266. Documents to be obtained by supplier of controlled drugs.

266. Documents to be obtained by supplier of controlled drugs.

Where a person ('the supplier'), not being a practitioner¹, supplies a controlled drug² otherwise than on a prescription³, he must not deliver the drug to a person who purports to be sent by or on behalf of the person to whom it is supplied ('the recipient⁴') and is not authorised⁵ to have that drug in his possession⁶, unless that person produces to the supplier a statement in writing signed by the recipient to the effect that he is empowered by the recipient to receive that drug on behalf of the recipient, and the supplier is reasonably satisfied that the document is a genuine document⁷.

Where a supplier supplies a controlled drug, otherwise than on a prescription or by way of administration, to any of the specified persons⁸, the supplier must not deliver the drug until he has obtained a requisition in writing⁹ and unless he is reasonably satisfied that the signature is that of the person purporting to have signed the requisition and that that person is engaged in the profession or occupation specified in the requisition¹⁰.

Where the person responsible for the dispensing and supply of medicines at any hospital or nursing home supplies a controlled drug to the sister or acting sister¹¹ for the time being in charge of any ward, theatre or other department in that hospital or nursing home ('the recipient'), he must obtain a requisition in writing, signed by the recipient, which specifies the total quantity of the drug to be supplied¹² and mark the requisition in such manner as to show that it has been complied with¹³.

Nothing in these provisions has effect in relation to specified drugs¹⁴ or any exempt product¹⁵.

1 For the meaning of 'practitioner' see PARA 243 note 9 ante.

2 For the meaning of 'controlled drug' see PARA 238 ante.

3 'Prescription' means a prescription issued by a doctor, a supplementary prescriber or an extended formulary nurse prescriber for the medical treatment of a single individual, by a dentist for the dental treatment of a single individual, or by a veterinary surgeon or veterinary practitioner for the purposes of animal treatment: Misuse of Drugs Regulations 2001, SI 2001/3998, reg 2(1). For the meanings of 'doctor', 'dentist', 'veterinary surgeon' and 'veterinary practitioner' see PARA 243 note 9 ante. For the meaning of 'supplementary prescriber' see PARA 251 note 15 ante. For the meaning of 'extended formulary nurse prescriber' see PARA 251 note 22 ante.

4 Ibid reg 14(1)(a).

5 I.e. by any provision of the Misuse of Drugs Regulations 2001, SI 2001/3998 (as amended), other than the provisions of reg 6(6), (7)(f): see PARA 253 ante.

6 Ibid reg 14(1)(b).

7 Ibid reg 14(1).

8 The specified persons are: a practitioner; the person in charge or acting person in charge of a hospital or nursing home; a person who is in charge of a laboratory; the owner of a ship, or the master of a ship which does not carry a doctor among the seamen employed in it; the master of a foreign ship in a port in Great Britain; the installation manager of an offshore installation; and a supplementary prescriber: ibid reg 14(4)(a)-(g) (reg 14(g) added by SI 2005/271). For the meanings of 'master', 'seamen', 'installation manager' and 'offshore installation' see PARA 251 note 21 ante. For the meaning of 'Great Britain' see PARA 7 note 3 ante.

9 Misuse of Drugs Regulations 2001, SI 2001/3998, reg 14(2)(a). The requisition must be signed by the person to whom the drug is supplied ('the recipient') (reg 14(2)(a)(i)); state the name, address and profession or occupation of the recipient (reg 14(2)(a)(ii)); specify the purpose for which the drug supplied is required and the

total quantity to be supplied (reg 14(2)(a)(iii)); and, where appropriate, satisfy additional requirements (reg 14(2)(a)(iv)). The additional requirements are that the requisition must, where furnished by the person in charge or acting person in charge of a hospital or nursing home, be signed by a doctor or dentist employed or engaged in that hospital or nursing home (reg 14(5)(a)); and, where furnished by the master of a foreign ship, contain a statement, signed by the proper officer of the port health authority within whose jurisdiction the ship is, that the quantity of the drug to be supplied is the quantity necessary for the equipment of the ship (reg 14(5)(b)). As to port health authorities see ENVIRONMENTAL QUALITY AND PUBLIC HEALTH vol 45 (2010) PARAS 102, 103.

10 Ibid reg 14(2)(b). However, where the recipient is a practitioner and he represents that he urgently requires a controlled drug for the purpose of his profession, the supplier may, if he is reasonably satisfied that the recipient so requires the drug and is, by reason of some emergency, unable before delivery to furnish to the supplier a requisition in writing duly signed, deliver the drug to the recipient on an undertaking by the recipient to furnish such a requisition within the 24 hours next following: reg 14(2). A person who has given such an undertaking must deliver to the person by whom the controlled drug was supplied a signed requisition in accordance with the undertaking: reg 14(3).

11 For the meaning of 'sister or acting sister' see PARA 251 note 7 ante.

12 Misuse of Drugs Regulations 2001, SI 2001/3998, reg 14(6)(a).

13 Ibid reg 14(6)(b). Any such requisition must be retained in the dispensary at which the drug was supplied and a copy of the requisition or a note of it must be retained or kept by the recipient: reg 14(6).

14 Ie (1) the drugs specified in ibid Schs 4 and 5 or poppy-straw (reg 14(7)(a)); (2) any drug specified in Sch 3 contained in or comprising a preparation which: (a) is required for use as a buffering agent in chemical analysis (reg 14(7)(b)(i)); (b) has present in it both a substance specified in Sch 3 para 1 or 2 and a salt of that substance (reg 14(7)(b)(ii)); and (c) is pre-mixed in a kit (reg 14(7)(b)(iii)). For the meaning of 'poppy-straw' see PARA 239 note 7 ante.

15 Ibid reg 14(7)(c). For the meaning of 'exempt product' see PARA 249 note 4 ante.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

266 Documents to be obtained by supplier of controlled drugs

TEXT AND NOTES--For 'nursing home' read 'care home', and for 'sister or acting sister' read 'senior registered nurse or acting senior registered nurse': SI 2001/3998 reg 14(4)-(6) (amended by SI 2007/2154).

NOTE 9--Subject to SI 2001/3998 reg 14(5B), on receipt of a requisition, other than a veterinary requisition, the supplier must mark on the requisition in ink or otherwise indelibly his name and address and send the requisition to the relevant National Health Service agency in accordance with arrangements specified by that agency: reg 14(5A) (added by SI 2007/2154). SI 2001/3998 reg 14(5A) does not apply where the supplier is a wholesale dealer or a person responsible for the dispensing and supply of medicine at a hospital or care home: reg 14(5B) (added by SI 2007/2154). 'Veterinary requisition' means a requisition which states that the recipient is a veterinary surgeon or veterinary practitioner: SI 2001/3998 reg 14(8) (added by SI 2007/2154).

NOTES 9, 10--SI 2001/3998 reg 14(2) amended: SI 2007/2154.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(3) THE CONTROL OF DRUGS/(ii) Prevention of Misuse of Controlled Drugs/267. Registers and records.

267. Registers and records.

Every person authorised¹ to supply any specified drug² must keep a register³ and must enter in it in chronological sequence in the form specified⁴ particulars of every quantity of such a drug obtained by him and of every quantity of such a drug supplied, whether by way of administration or otherwise, by him whether to persons within or outside Great Britain⁵. In the case of a drug supplied⁶ to him for the purpose of destruction, these provisions do not have effect in relation to a practitioner or pharmacist⁷, a person licensed⁸ to supply any drug (where the licence so directs)⁹, or the sister or acting sister¹⁰ for the time being in charge of a ward, theatre or other department in a hospital or nursing home¹¹. Any person required to keep such a register must comply with the prescribed requirements¹². All registers and books must be preserved for a period of two years from the date on which the last entry is made in them¹³.

Every person who is authorised¹⁴ to produce any specified drug¹⁵ must make a record of each quantity of such a drug produced by him¹⁶; every person who is authorised by or under any provision of the Misuse of Drugs Act 1971 to import or export any specified drug¹⁷ must make a record of each quantity of such a drug imported or exported by him¹⁸; and every person who is authorised¹⁹ to supply any specified drug²⁰ must make a record of each quantity of such a drug imported or exported by him²¹. Every such record must be preserved for a period of two years from the date on which the record was made²².

A producer of any specified drug²³ and a wholesale dealer²⁴ in any such drug must keep every invoice or other like record issued in respect of each quantity of such a drug obtained by him and in respect of each quantity of such a drug supplied by him²⁵. A person who is authorised²⁶ to supply any specified drug²⁷ must keep every invoice or other like record issued in respect of each quantity of such a drug obtained by him and in respect of each quantity of such a drug supplied by him²⁸; and a retail dealer²⁹ in any such drug, a person in charge or acting person in charge of a hospital or nursing home, and a person in charge of a laboratory, must keep every invoice or other like record issued in respect of each quantity of such a drug obtained by him and in respect of each quantity of such a drug supplied by him³⁰. A retail dealer in specified drugs³¹ must keep every invoice or other like record issued in respect of each quantity of such a drug obtained by him³².

Every requisition, order or prescription³³ on which a controlled drug³⁴ is supplied³⁵ must be preserved for a period of two years from the date on which the last delivery under it was made³⁶.

Nothing in these provisions has effect in relation to any exempt product³⁷.

1 le by or under the Misuse of Drugs Regulations 2001, SI 2001/3998, regs 5, 8: see PARA 251 ante.

2 le specified in *ibid* Schs 1, 2 (amended by SI 2003/1432). Specific requirements apply in respect of drugs in the Misuse of Drugs Regulations 2001, SI 2001/3998, Sch 2 (as amended) in particular circumstances: see reg 21.

3 He must use a separate register or separate part of the register for entries made in respect of each class of drugs, and each of the drugs specified in *ibid* Sch 1 paras 1, 3 and Sch 2 paras 1, 3 and 6 together with its salts and any preparation or other product containing it or any of its salts must be treated as a separate class, so however that any stereoisomeric form of a drug or its salts must be classed with that drug: reg 19(1)(b). However, nothing in this provision must be taken as preventing the use of a separate section within a register or separate part of a register in respect of different drugs or strengths of drugs comprised within the class of drugs to which that register or separate part relates: reg 19(2).

- 4 Ie specified in ibid Sch 6 Pt I or Sch 6 Pt II, as the case may require.
- 5 Ibid reg 19(1)(a). For the meaning of 'Great Britain' see PARA 7 note 3 ante.
- 6 Ie in pursuance of ibid reg 6(2), (3): see PARA 249 ante.
- 7 Ibid reg 19(3)(a). For the meaning of 'practitioner' see PARA 243 note 9 ante. For the meaning of 'pharmacist' see PARA 46 note 10 ante.
- 8 Ie under ibid reg 5: see PARA 251 ante.
- 9 Ibid reg 19(3)(b).
- 10 For the meaning of 'sister or acting sister' see PARA 251 note 7 ante.
- 11 Misuse of Drugs Regulations 2001, SI 2001/3998, reg 19(3)(c).
- 12 Ibid reg 20. As to the prescribed requirements see reg 20(a)-(g).
- 13 Ibid reg 23(1).
- 14 Ie under ibid reg 5 or reg 9(1)(c): see PARA 251 ante.
- 15 Ie specified in ibid Schs 3, 4.
- 16 Ibid reg 22(1).
- 17 Ie specified in ibid Sch 3.
- 18 Ibid reg 22(2). This provision does not have effect in relation to a person licensed under the Misuse of Drugs Act 1971 to import or export any drug where the licence so directs: Misuse of Drugs Regulations 2001, SI 2001/3998, reg 22(4). As to such licenses see PARA 248 ante.
- 19 Ie under ibid reg 9(4): see PARA 251 ante.
- 20 Ie specified in ibid Sch 4.
- 21 Ibid reg 22(3).
- 22 Ibid reg 23(2).
- 23 Ie specified in ibid Schs 3, 5.
- 24 'Wholesale dealer' means a person who carries on the business of selling drugs to persons who buy to sell again: ibid reg 2(1).
- 25 Ibid reg 24(1). Every invoice or other record which is required by reg 24 to be kept in respect of a drug specified in Sch 3 must contain information sufficient to identify the date of the transaction and the person by whom or to whom the drug was supplied: reg 24(5). Every document kept in pursuance of reg 24 (other than a health prescription) must be preserved for a period of two years from the date on which it is issued, except that the keeping of a copy of the document made at any time during the said period of two years is treated for these purposes as if it were the keeping of the original document: reg 24(6). 'Health prescription' means a prescription issued by a doctor or a dentist under the National Health Service Act 1977: Misuse of Drugs Regulations 2001, SI 2001/3998, reg 2(1). For the meaning of 'prescription' see PARA 266 note 3 ante. For the meanings of 'doctor' and 'dentist' see PARA 243 note 9 ante.
- 26 Ie under ibid reg 9(4)(a): see PARA 251 ante.
- 27 Ie specified in ibid Sch 3.
- 28 Ibid reg 24(2). See also note 25 supra.
- 29 'Retail dealer' means a person lawfully conducting a retail pharmacy business or a pharmacist engaged in supplying drugs to the public at a health centre: ibid reg 2(1). For the meaning of 'person lawfully conducting a retail pharmacy business' see PARA 250 note 6 ante. For the meaning of 'health centre' see PARA 51 note 9 ante; definition applied by reg 2(1).

- 30 Ibid reg 24(3). See also note 25 supra.
- 31 Ie specified in ibid Sch 5.
- 32 Ibid reg 24(4). See also note 25 supra.
- 33 This requirement does not apply to a health prescription: ibid reg 23(3).
- 34 For the meaning of 'controlled drug' see PARA 238 ante.
- 35 Ie in pursuance of the Misuse of Drugs Regulations 2001, SI 2001/3998 (as amended).
- 36 Ibid reg 23(3).
- 37 Ibid reg 25. For the meaning of 'exempt product' see PARA 249 note 4 ante.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

267 Registers and records

NOTE 2--See also SI 2001/3998 reg 19(1)(c) (added by SI 2006/1450); and SI 2001/3998 reg 19(1)(d)-(f) (added by SI 2007/2154).

TEXT AND NOTE 3--'Register' means either a bound book, which does not include any form of loose leaf register or card index, or a computerised system which is in accordance with best practice guidance indorsed by the Secretary of State under the National Health Service Act 1977 s 2: SI 2001/3998 reg 2(1) (definition substituted by SI 2005/2864).

NOTE 3--Entries made in respect of drugs obtained and drugs supplied may be made on the same page or on separate pages in the register: SI 2001/3998 reg 19(2) (substituted by SI 2007/2154). Nothing, subject to specified provisions, is to prevent the use of a register to record additional information to that required or allowed under those specified provisions: SI 2001/3998 reg 19(2A) (added by SI 2006/1450; and amended by SI 2007/2154).

NOTE 4--SI 2001/3998 Sch 6 revoked: SI 2007/2154.

NOTE 5--SI 2001/3998 reg 19(1)(a) amended: SI 2007/2154.

TEXT AND NOTES 10, 11, 30--For 'nursing home' read 'care home', and for 'sister or acting sister' read 'senior registered nurse or acting senior registered nurse': SI 2001/3998 regs 19(3), 24(3) (amended by SI 2007/2154).

NOTE 12--SI 2001/3998 reg 20(d) substituted, reg 20(g) amended: SI 2005/2864. SI 2001/3998 reg 20(a) substituted: SI 2007/2154.

NOTES 15, 20--SI 2001/3998 Sch 4 further amended: SI 2007/2154.

NOTE 17--SI 2001/3998 Sch 3 further amended: see PARA 249 NOTE 6.

NOTES 22, 25--For the purposes of SI 2001/3998 regs 23 and 24(6), 'preserved' means kept in its original form, or copied and kept in a computerised form which is in accordance with best practice guidance indorsed by the Secretary of State under the 1977 Act s 2: SI 2001/3998 reg 24A (added by SI 2005/2864).

TEXT AND NOTE 36--Every veterinary prescription on which a controlled drug is supplied and every prescription, other than a health prescription, on which a specified controlled drug is so supplied must be preserved for a period of two years from the date on which the last delivery under it was made: SI 2001/3998 reg 23(3) (amended by SI 2006/2178, SI 2007/2154). Every prescription, other than a health prescription, or a veterinary prescription, on which a controlled drug, other than specified drugs, or a copy of such prescription, must be sent to the relevant National Health Service agency in accordance with arrangements specified by that agency: SI 2001/3998 reg 23(4) (added by SI 2006/1450 and amended by SI 2006/2178, SI 2007/2154).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(3) THE CONTROL OF DRUGS/(ii) Prevention of Misuse of Controlled Drugs/268. Information.

268. Information.

Certain persons¹ must, on demand made by the Secretary of State² or by any person authorised in writing by the Secretary of State in that behalf, furnish such particulars as may be requested in respect of the producing, obtaining or supplying by him of any controlled drug or in respect of any stock of such drugs in his possession³; for the purpose of confirming any such particulars, produce any stock of such drugs in his possession⁴; and produce any register, book or document required to be kept relating to any dealings in controlled drugs which is in his possession⁵. However, these provisions do not require the furnishing of personal records⁶ which a person has acquired or created in the course of his profession or occupation and which he holds in confidence⁷.

If it appears to the Secretary of State that there exists in any area in Great Britain⁸ a social problem caused by the extensive misuse⁹ of dangerous or otherwise harmful drugs in that area, he may by notice in writing served¹⁰ on any doctor¹¹ or pharmacist¹² practising in or in the vicinity of that area, or on any person¹³ carrying on a retail pharmacy business¹⁴ at any premises situated in or in the vicinity of that area, require him to furnish information to the Secretary of State relating to the quantities in which and the number and frequency of the occasions on which the drugs specified in the notice have been prescribed, administered or supplied during the period specified in the notice¹⁵. Failure to comply with the requirements set out in such a notice without reasonable excuse is an offence¹⁶. It is also an offence if a person in purported compliance with any such requirement gives any information which he knows to be false in a material particular or if he recklessly gives any information which is false in a material particular¹⁷.

1 The persons are: any person authorised by or under the Misuse of Drugs Regulations 2001, SI 2001/3998 (as amended) to produce any controlled drug (reg 26(2)(a)); any person authorised by or under any provision of the Misuse of Drugs Act 1971 to import or export any controlled drug (Misuse of Drugs Regulations 2001, SI 2001/3998, reg 26(2)(b)); a wholesale dealer (reg 26(2)(c)); a retail dealer (reg 26(2)(d)); a practitioner (reg 26(2)(e)); the person in charge or acting person in charge of a hospital or nursing home (reg 26(2)(f)); a person who is in charge of a laboratory (reg 26(2)(g)); a person who is authorised under reg 9(4)(a) (see PARA 251 ante) to supply any controlled drug (reg 26(2)(h)); and a supplementary prescriber (reg 26(2)(i) (added by SI 2005/271)). For the meaning of 'controlled drug' see PARA 238 ante. For the meaning of 'wholesale dealer' see PARA 267 note 24 ante; and for the meaning of 'retail dealer' see PARA 267 note 29 ante. For the meaning of 'practitioner' see PARA 243 note 9 ante. For the meaning of 'supplementary prescriber' see PARA 251 note 15 ante.

2 As to the Secretary of State see PARA 3 note 3 ante.

3 Misuse of Drugs Regulations 2001, SI 2001/3998, reg 26(1)(a).

4 Ibid reg 26(1)(b).

5 Ibid reg 26(1)(c). As to the requirements relating to registers and records see PARA 267 ante.

6 'Personal records' means documentary and other records concerning an individual (whether living or dead) who can be identified from them and relating to his physical or mental health: ibid reg 26(3).

7 Ibid reg 26(3).

8 For the meaning of 'Great Britain' see PARA 7 note 3 ante.

9 As to references to misusing a drug see PARA 246 note 5 ante.

10 As to the service of notices see PARA 245 ante.

11 For the meaning of 'doctor' see PARA 243 note 9 ante.

12 For the meaning of 'pharmacist' see PARA 46 note 10 ante.

13 For the meaning of 'person' see PARA 21 note 7 ante.

14 For the meaning of 'retail pharmacy business' see PARA 51 note 3 ante; definition applied by the Misuse of Drugs Act 1971 s 17(1).

15 Ibid s 17(1). Such a notice may require the particulars requested to be furnished in a specified manner and within a specified period, and may require a pharmacist or person carrying on a retail pharmacy business to furnish the names and addresses of doctors on whose prescriptions any dangerous or otherwise harmful drugs to which the notice relates were supplied, but must not require any person to furnish particulars relating to the identity of any person for or to whom any such drug has been prescribed, administered or supplied: s 17(2).

16 Ibid s 17(3). Proof of reasonable excuse lies on the accused: s 17(3). As to the standard of proof see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(3) (2006 Reissue) PARA 1372. The penalty for this offence on summary conviction is a fine of level 3 on the standard scale: s 25(1), (2), Sch 4 (amended by virtue of the Criminal Justice Act 1982 s 46). As to the standard scale see PARA 6 note 22 ante.

17 Misuse of Drugs Act 1971 s 17(4). The penalty for this offence on summary conviction is imprisonment for a term not exceeding six months or a fine not exceeding the prescribed sum or both, and on conviction on indictment is imprisonment for a term not exceeding two years or a fine or both: Sch 4 (amended by virtue of the Magistrates' Courts Act 1980 s 32(2)). As to the prescribed sum see PARA 32 note 3 ante.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

268 Information

NOTE 1--For 'nursing home' read 'care home': SI 2001/3998 reg 26(2)(f) (amended by SI 2007/2154).

TEXT AND NOTE 5--For the purposes of SI 2001/3998 reg 26(1)(c), the Secretary of State or any person authorised in writing by the Secretary of State in that behalf may request that a register which is kept in computerised form be produced by sending a copy of it, in computerised or other form, to the appropriate person: SI 2001/3998 reg 26(1A) (added by SI 2005/2864).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(3) THE CONTROL OF DRUGS/(ii) Prevention of Misuse of Controlled Drugs/269. Marking of bottles or other containers.

269. Marking of bottles or other containers.

No person may supply a controlled drug¹ otherwise than in a bottle, package or other container which is plainly marked². In the case of a controlled drug other than a preparation, it must be marked with the amount of the drug contained therein³. In the case of a controlled drug which is a preparation made up into tablets, capsules or other dosage units, it must be marked with the amount of each component, being a controlled drug, of the preparation in each dosage unit and the number of dosage units in the bottle, package or other container⁴; and in the case of one not so made up, it must be marked with the total amount of the preparation in the bottle, package or other container and the percentage of each of its components which is a controlled drug⁵.

1 Nothing in the Misuse of Drugs Regulations 2001, SI 2001/3998, reg 18 has effect in relation to: (1) the drugs specified in Schs 4 and 5 or poppy-straw (reg 18(2)(a)); (2) any drug specified in Sch 3 contained in or comprising a preparation which is required for use as a buffering agent in chemical analysis, has present in it both a substance specified in Sch 3 para 1 or 2 and a salt of that substance, and is pre-mixed in a kit (reg 18(2)(b)); (3) any exempt product; (4) the supply of a controlled drug by or on the prescription of a practitioner or supplementary prescriber; (5) the supply of a controlled drug for administration in a clinical trial or a medicinal test on animals (reg 18(2)(e) (added by SI 2005/271)). For the meaning of 'poppy-straw' see PARA 239 note 7 ante. For the meaning of 'exempt product' see PARA 249 note 4 ante. For the meaning of 'controlled drug' see PARA 238 ante. For the meaning of 'prescription' see PARA 266 note 3 ante. For the meaning of 'practitioner' see PARA 243 note 9 ante. For the meaning of 'supplementary prescriber' see PARA 251 note 15 ante. For the meaning of 'clinical trial' see PARA 82; and for the meaning of 'medicinal test on animals' see PARA 126 ante (definitions applied by reg 18(3) (substituted by SI 2004/1031)).

2 Misuse of Drugs Regulations 2001, SI 2001/3998, reg 18(1).

3 Ibid reg 18(1)(a).

4 Ibid reg 18(1)(b)(i).

5 Ibid reg 18(1)(b)(ii).

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(3) THE CONTROL OF DRUGS/(ii) Prevention of Misuse of Controlled Drugs/270. Supply of controlled drugs on prescription.

270. Supply of controlled drugs on prescription.

A person must not issue a prescription¹ containing a controlled drug² unless the prescription complies with the prescribed requirements³. A person must not supply a controlled drug⁴ on a prescription: (1) unless the prescription complies with those requirements⁵; (2) unless the address specified in the prescription as the address of the person issuing it is an address within the United Kingdom⁶; (3) unless he either is acquainted with the signature of the person by whom it purports to be issued and has no reason to suppose that it is not genuine, or has taken reasonably sufficient steps to satisfy himself that it is genuine⁷; (4) before the date specified in the prescription⁸; or (5) later than 13 weeks after the date specified in the prescription⁹. A person supplying on prescription a controlled drug¹⁰ must, at the time of the supply, mark on the prescription the date on which the drug is supplied and, unless it is a health prescription¹¹, must retain the prescription on the premises from which the drug was supplied¹².

Nothing in these provisions has effect in relation to a prescription issued for the purposes of a scheme for testing the quality or amount of the drugs, preparations and appliances supplied under the National Health Service Act 1977 and the regulations made thereunder or to any prescriptions issued for the purposes of the Medicines Act 1968 to a sampling officer¹³.

1 For the meaning of 'prescription' see PARA 266 note 3 ante.

2 I.e. other than a drug specified in the Misuse of Drugs Regulations 2001, SI 2001/3998, Sch 4 or Sch 5 (Sch 4 amended by SI 2003/1432) or temazepam: Misuse of Drugs Regulations 2001, SI 2001/3998, reg 15(1). For the meaning of 'controlled drug' see PARA 238 ante.

3 Ibid reg 15(1). As to the prescribed requirements see reg 15(1)-(3).

4 I.e. other than a drug specified in ibid Schs 4 (as amended), 5.

5 Ibid reg 16(1)(a).

6 Ibid reg 16(1)(b). For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

7 Ibid reg 16(1)(c).

8 Ibid reg 16(1)(d).

9 Ibid reg 16(1)(e) (amended by SI 2003/1653). In the case of a prescription containing a controlled drug other than a drug specified in the Misuse of Drugs Regulations 2001, SI 2001/3998, Sch 4 or Sch 5, which contains a direction that specified instalments of the total amount may be supplied at stated intervals, the person supplying the drug must not do so otherwise than in accordance with that direction, and reg 16(1) (as amended) has effect as if for the requirement contained in reg 16(1)(e) (as amended) there were substituted a requirement that the occasion on which the first instalment is supplied must not be later than 13 weeks after the date specified in the prescription: reg 16(4)(a).

10 I.e. other than a drug specified in ibid Schs 4 (as amended), 5.

11 For the meaning of 'health prescription' see PARA 267 note 25 ante.

12 Misuse of Drugs Regulations 2001, SI 2001/3998, reg 16(2). In the case of a prescription containing a controlled drug other than a drug specified in Sch 4 (as amended) or Sch 5, which contains a direction that specified instalments of the total amount may be supplied at stated intervals, the person supplying the drug must not do so otherwise than in accordance with that direction, and reg 16(2) has effect as if for the words 'at the time of the supply' there were substituted the words 'on each occasion on which an instalment is supplied': reg 16(4)(b). Specific requirements apply in the case of the supplying temazepam on prescription: see reg

16(3). As to the general requirements relating to the retention of prescriptions and other records see PARA 267 ante.

13 Ibid reg 17. As to sampling officers see PARA 171 ante.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

270 Supply of controlled drugs on prescription

TEXT AND NOTES--A person must not issue a prescription other than a health prescription or a veterinary prescription containing temazepam unless it is written on a specified prescription form: SI 2001/3998 reg 15(1A) (added by SI 2006/1450 and amended by SI 2006/2178). Nothing in SI 2001/3998 reg 15 prevents the issue of a prescription other than a health prescription which is not on a specified prescription form containing a controlled drug other than a drug specified in Schs 4 or 5 where the person issuing the prescription believes on reasonable grounds that the drug will be supplied by a pharmacist in a hospital: reg 15(1B) (added by SI 2006/1450). A pharmacist may supply a controlled drug other than a drug specified in Schs 4 or 5 or temazepam if the prescription contains minor typographical errors or spelling mistakes or if it does not comply with the provisions of SI 2001/3998 reg 15 in a specified way provided that certain conditions are met: reg 16(1A), (1B) (added by SI 2006/1450). A pharmacist may supply a controlled drug other than a drug specified in SI 2001/3998 Schs 4 or 5 on a prescription other than a health prescription in a hospital if it does not comply with reg 15 in a specified way: reg 16(1C), (1D) (added by SI 2006/1450). A person must not supply a controlled drug specified in SI 2001/3998 Sch 4 on a prescription later than 28 days after the appropriate date: reg 16(5) (added by SI 2006/1450). 'Appropriate date' means later of the date on which it was signed by the person issuing it or the date indicated by him as being the date before which it must not be supplied: SI 2001/3998 reg 16(7) (added by SI 2006/1450). A person who is asked to supply on prescription a controlled drug specified in SI 2001/3998 Sch 2 (amended: see PARA 251 NOTE 16) must first ascertain whether the person collecting the drug is the patient, the patient's representative or a healthcare professional acting in his professional capacity on behalf of the patient and (1) where that person is the patient or the patient's representative he may request evidence of that person's identity and refuse to supply the drug if he is not satisfied as to the identity of that person (SI 2001/3998 reg 16(6) (a)); and (2) where that person is a healthcare professional acting in his professional capacity on behalf of the patient, he must obtain that person's name and address, unless he is acquainted with that person, request evidence of that person's identity, but may supply the drug even if he is not satisfied as to the identity of that person (reg 16(6)(b)): reg 16(6) (added by SI 2006/1450).

NOTE 2--SI 2001/3998 reg 15(1) amended: SI 2006/1450. SI 2001/3998 Sch 4 further amended: SI 2005/3372, SI 2007/2154. SI 2001/3998 Sch 5 amended: SI 2005/2864, SI 2007/2154.

NOTE 3--SI 2001/3998 reg 15(1) amended, reg 15(2) revoked: SI 2005/2864. SI 2001/3998 reg 15(3) amended: SI 2007/2154.

TEXT AND NOTE 11--For 'unless it is a health prescription' read 'if it is a veterinary prescription': SI 2001/3998 reg 16(2) (amended by SI 2006/2178).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(3) THE CONTROL OF DRUGS/(ii) Prevention of Misuse of Controlled Drugs/271. Addiction regulations.

271. Addiction regulations.

A doctor¹ must not administer or supply to a person who he considers, or has reasonable grounds to suspect, is addicted² to any drug³, or authorise the administration or supply to such a person of any specified substance⁴, or prescribe for such a person any such substance, except for the purpose of treating organic disease or injury⁵ or under and in accordance with the terms of a licence issued⁶ by the Secretary of State⁷. However, these provisions do not apply to the administration or supply by a doctor of a specified substance⁸ if the administration or supply is authorised by another doctor under and in accordance with the terms of such a licence issued to him⁹.

These regulations¹⁰ relating to the supply of drugs to addicts apply to servants and agents of the Crown¹¹.

1 For the meaning of 'doctor' see PARA 243 note 9 ante.

2 A person must be regarded as being addicted to a drug if, and only if, he has as a result of repeated administration become so dependent upon the drug that he has an overpowering desire for the administration of it to be continued: Misuse of Drugs (Supply to Addicts) Regulations 1997, SI 1997/1001, reg 2(2). As to the powers of a police officer to require a person in detention to submit to an assessment to establish whether that person is dependent upon or has a propensity to misuse a Class A drug see the Drugs Act 2005 Pt 3 (ss 9-19); and CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(1) (2006 Reissue) PARA 65.

3 'Drug' means a controlled drug specified in the Misuse of Drugs (Supply to Addicts) Regulations 1997, SI 1997/1001, Schedule: reg 2(1). For the meaning of 'controlled drug' see PARA 238 ante.

4 The specified substances are: (1) cocaine, its salts and any preparation or other product containing cocaine or its salts other than a preparation falling within the Misuse of Drugs Regulations 1985, SI 1985/2066, Sch 5 para 2 (revoked: see now the Misuse of Drugs Regulations 2001, SI 2001/3998, Sch 5) (Misuse of Drugs (Supply to Addicts) Regulations 1997, SI 1997/1001, reg 3(3)(a)); (2) diamorphine, its salts and any preparation or other product containing diamorphine or its salts (reg 3(3)(b)); (3) dipipanone, its salts and any preparation or other product containing dipipanone or its salts (reg 3(3)(c)).

5 Ibid reg 3(1)(a).

6 Ie in pursuance of the Misuse of Drugs (Supply to Addicts) Regulations 1997, SI 1997/1001. Notwithstanding the revocation of the Misuse of Drugs (Notification of and Supply to Addicts) Regulations 1973, SI 1973/799, any licence issued by the Secretary of State in pursuance of those regulations before 1 May 1997 continues in force and is deemed to have been issued in pursuance of the Misuse of Drugs (Supply to Addicts) Regulations 1997, SI 1997/1001: reg 5(2). As to licences generally see PARA 244 ante.

7 Ibid reg 3(1)(b). As to the Secretary of State see PARA 3 note 3 ante. As to prohibitions in respect of practitioners contravening the addiction regulations see PARA 273 post.

8 See note 4 supra.

9 Misuse of Drugs (Supply to Addicts) Regulations 1997, SI 1997/1001, reg 3(2).

10 Ie the Misuse of Drugs (Supply to Addicts) Regulations 1997, SI 1997/1001, and, in relation only to the requirements of such regulations, the Misuse of Drugs Act 1971 s 13(1), (3) (see PARA 273 post), ss 14, 16 (see PARA 274 post), ss 19, 25, Sch 4 (see PARA 260 ante), which relate to their enforcement.

11 Misuse of Drugs (Supply to Addicts) Regulations 1997, SI 1997/1001, reg 4.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

271 Addiction regulations

NOTE 4--Head (1). Words 'other than ... SI 2001/3998, Sch 5' omitted: SI 1997/1001 reg 3(3)(a) (substituted by SI 2005/2864).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(4) DIRECTIONS TO PRACTITIONERS AND PHARMACISTS/272. Prohibitions in respect of convicted practitioners and pharmacists.

(4) DIRECTIONS TO PRACTITIONERS AND PHARMACISTS

272. Prohibitions in respect of convicted practitioners and pharmacists.

The Secretary of State¹ may give a direction in respect of any practitioner² or pharmacist³ who has after 30 June 1973⁴ been convicted of an offence⁵ under the Misuse of Drugs Act 1971 or under the Dangerous Drugs Act 1965⁶, or of an offence under certain provisions of the customs and excise legislation⁷, or of an offence under the Criminal Justice (International Co-operation) Act 1990⁸.

In the case of a practitioner, the direction is that he be prohibited from having in his possession, prescribing, administering, manufacturing, compounding and supplying⁹ and from authorising the administration and supply of such controlled drugs¹⁰ as may be specified in the direction¹¹. In the case of a pharmacist, the direction is that he be prohibited from having in his possession, manufacturing, compounding and supplying and from supervising and controlling the manufacture, compounding and supply of such controlled drugs as may be so specified¹².

Any such direction takes effect when a copy of it is served¹³ on the person to whom it applies¹⁴. In addition to causing a copy to be so served, the Secretary of State must cause notice of the direction to be published in the London, Edinburgh and Belfast Gazettes¹⁵. He may at any time give a further direction cancelling or suspending the direction, or cancelling any further direction suspending another direction¹⁶.

It is an offence to contravene¹⁷ any such direction¹⁸.

1 As to the Secretary of State see PARA 3 note 3 ante.

2 For the meaning of 'practitioner' see PARA 243 note 9 ante.

3 For the meaning of 'pharmacist' see PARA 46 note 10 ante.

4 Ie after the coming into force of the relevant provisions of the Misuse of Drugs Act 1971: Misuse of Drugs Act 1971 (Commencement No 2) Order 1973, SI 1973/795.

5 This reference to an 'offence' includes references to an attempted offence under the Criminal Attempts Act 1981 s 1: s 7(3). As to attempts to commit an offence see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(1) (2006 Reissue) PARA 79.

6 Misuse of Drugs Act 1971 s 12(1)(a). The Dangerous Drugs Act 1965 was repealed by the Misuse of Drugs Act 1971 s 39(2), Sch 6. Section 12 refers also to any enactment repealed by the Dangerous Drugs Act 1965.

7 Ie an offence under the Customs and Excise Act 1952 s 45, s 56 or s 304 (all repealed), or under the Customs and Excise Management Act 1979 s 50, s 68 or s 170 (all as amended), in connection with a prohibition of or restriction on importation or exportation of a controlled drug having effect by virtue of the Misuse of Drugs Act 1971 s 3 (see PARA 248 ante), or which had effect by virtue of any provision contained in or repealed by the Dangerous Drugs Act 1965: Misuse of Drugs Act 1971 s 12(1)(b) (amended by the Customs and Excise Management Act 1979 s 177(1), Sch 4 para 8).

8 Misuse of Drugs Act 1971 s 12(1)(c) (added by the Criminal Justice (International Co-operation) Act 1990 s 23(2)). The offence referred to in the text is an offence under the Criminal Justice (International Co-operation) Act 1990 ss 12, 13: see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARA 773.

9 As to the meaning 'supplying' see PARA 249 note 5 ante.

10 For the meaning of 'controlled drug' see PARA 238 ante.

11 Misuse of Drugs Act 1971 s 12(2)(a).

12 Ibid s 12(2)(b).

13 As to the service of documents see PARA 245 ante.

14 Misuse of Drugs Act 1971 s 12(5).

15 Ibid s 12(4).

16 Ibid s 12(3).

17 For the meaning of 'contravene' see PARA 249 note 9 ante.

18 Misuse of Drugs Act 1971 s 12(6). In cases concerning a Class A or Class B drug (see PARAS 238-240 ante), a person is liable on summary conviction to imprisonment for a term not exceeding six months or to a fine not exceeding the prescribed sum or to both, or on conviction on indictment to imprisonment for a term not exceeding 14 years or to a fine or to both: s 25(1), (2), Sch 4 (amended by virtue of the Magistrates' Courts Act ss 31(1)-(3), 32(2)). As to the prescribed sum see PARA 32 note 3 ante. In cases concerning a Class C drug (see PARAS 238, 241 ante), a person is liable on summary conviction to imprisonment for a term not exceeding three months or to a fine of £2,500 or both, or on conviction on indictment to imprisonment for a term not exceeding 14 years or to a fine or both: Misuse of Drugs Act 1971 Sch 4 (amended by the Criminal Law Act 1977 s 28(8), Sch 5; the Criminal Justice and Public Order Act 1994 s 157(2), (4), Sch 8 Pt II; and the Criminal Justice Act 2003 s 284, Sch 28 para 1).

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(4) DIRECTIONS TO PRACTITIONERS AND PHARMACISTS/273. Prohibitions in respect of practitioners contravening addiction regulations or acting irresponsibly.

273. Prohibitions in respect of practitioners contravening addiction regulations or acting irresponsibly.

If a doctor¹ contravenes² regulations relating to the treatment of addicts³ or if he contravenes the terms of a licence issued under such regulations, the Secretary of State⁴ may give a direction prohibiting that doctor from prescribing, administering and supplying⁵ such controlled drugs⁶ as may be specified in the direction and from authorising the administration and supply of such drugs⁷. If the Secretary of State is of the opinion that a practitioner is or has after 1 July 1973⁸ been prescribing, administering or supplying or authorising the administration or supply of any controlled drug in an irresponsible manner, he may give a similar direction prohibiting that practitioner from prescribing, administering and supplying the controlled drugs specified in the direction and from authorising the administration and supply of such drugs⁹.

It is an offence to contravene any such direction¹⁰.

1 For the meaning of 'doctor' see PARA 243 note 9 ante.

2 For the meaning of 'contravene' see PARA 249 note 9 ante.

3 I.e. regulations made under the Misuse of Drugs Act 1971 s 10(2)(h), (i): see PARA 263 ante. As to such regulations see the Misuse of Drugs (Supply to Addicts) Regulations 1997, SI 1997/1001; and PARA 271 ante. It is not an offence to contravene such regulations or the terms of such a licence, but it is an offence to contravene a direction given by the Secretary of State under the Misuse of Drugs Act 1971 s 13(1) or (2): s 13(3). For the meaning of 'contravene' see PARA 249 note 9 ante.

4 As to the Secretary of State see PARA 3 note 3 ante.

5 As to the meaning 'supplying' see PARA 249 note 5 ante.

6 For the meaning of 'controlled drug' see PARA 238 ante.

7 Misuse of Drugs Act 1971 s 13(1). The Secretary of State must exercise his powers subject to and in accordance with s 14 (see PARA 274 post): s 13(1). A direction given under this power takes effect when a copy of it is served on the person to whom it applies: s 16(4). As to the service of documents see PARA 245 ante.

8 I.e. the date on which *ibid* s 13(2) came into effect: Misuse of Drugs Act 1971 (Commencement No 2) Order 1973, SI 1973/795.

9 Misuse of Drugs Act 1971 s 13(2). The Secretary of State must exercise his powers subject to and in accordance with ss 14, 15 (see PARAS 274-275 post): s 13(2). A direction given under this power takes effect when a copy of it is served on the person to whom it applies: s 16(4).

10 *Ibid* s 13(3). In cases concerning a Class A or Class B drug (see PARAS 238-240 ante), a person is liable on summary conviction to imprisonment for a term not exceeding six months or to a fine not exceeding the prescribed sum or to both, or on conviction on indictment to imprisonment for a term not exceeding 14 years or to a fine or to both: s 25(1), (2), Sch 4 (amended by virtue of the Magistrates' Courts Act 1980 ss 31(1)-(3), 32(2)). As to the prescribed sum see PARA 32 note 3 ante. In cases concerning a Class C drug (see PARAS 238, 241 ante), a person is liable on summary conviction to imprisonment for a term not exceeding three months or to a fine of £2,500 or both, or on conviction on indictment to imprisonment for a term not exceeding 14 years or to a fine or both: Misuse of Drugs Act 1971 Sch 4 (amended by the Criminal Law Act 1977 s 28(8), Sch 5; the Criminal Justice and Public Order Act 1994 s 157(2), (4), Sch 8 Pt II; and the Criminal Justice Act 2003 s 284, Sch 28 para 1).

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(4) DIRECTIONS TO PRACTITIONERS AND PHARMACISTS/274. References to tribunals and advisory bodies.

274. References to tribunals and advisory bodies.

If the Secretary of State¹ considers that there are grounds for giving a direction² on account of the contravention³ by a doctor⁴ of regulations relating to the treatment of addicts or the terms of a licence issued under such regulations, or for giving a direction⁵ on account of a practitioner⁶ prescribing, administering or supplying⁷ or authorising the administration or supply of any controlled drug⁸ in an irresponsible manner, he may refer the case to a tribunal⁹ constituted for the purpose; and it is the duty of the tribunal to consider the case and report on it to the Secretary of State¹⁰.

Where the tribunal finds that there has been no such contravention by the doctor in question or where it finds that the practitioner in question has not conducted himself irresponsibly, or it finds that there has been a contravention or irresponsible conduct but does not recommend the giving of a direction¹¹, the Secretary of State must cause notice to that effect to be served¹² on the respondent¹³.

Where, on the other hand, the tribunal finds that there has been a contravention or irresponsible conduct and considers that a direction¹⁴ should be given in respect of the respondent, it must include in its report a recommendation to that effect indicating the controlled drugs which it considers should be specified in the direction or indicating that the direction should specify all controlled drugs¹⁵. In such a case, the Secretary of State must cause a notice to be served on the respondent stating whether or not he proposes to give a direction pursuant to the tribunal's recommendation¹⁶, and, where he does so propose, the notice must set out the terms of the proposed direction¹⁷ and inform the respondent that consideration will be given to any representations relating to the case made by him in writing¹⁸ to the Secretary of State within the period of 28 days beginning with the date of service of the notice¹⁹. If any such representations are received within that period, the Secretary of State must refer the case to an advisory body constituted for the purpose²⁰, which must consider the case and advise the Secretary of State as to the exercise of his powers²¹.

After the period of 28 days has expired and, in the case of a reference to an advisory body, after considering the advice of that body, the Secretary of State may: (1) give a direction²² in respect of the respondent specifying all or any of the controlled drugs indicated in the tribunal's recommendation²³; or (2) order that the case be referred back to the tribunal or referred to another properly constituted tribunal²⁴; or (3) order that no further proceedings be taken in the case²⁵. The Secretary of State must cause a copy of any such order or direction²⁶ to be served on the person to whom it applies and must cause notice of any such direction to be published in the London, Edinburgh and Belfast Gazettes²⁷. The Secretary of State may at any time give a direction cancelling or suspending any earlier direction²⁸ given by him or cancelling any direction by which a direction so given was suspended²⁹, and in such a case similar provisions as to notice and publication apply³⁰.

1 As to the Secretary of State see PARA 3 note 3 ante.

2 Ie under the Misuse of Drugs Act 1971 s 13(1): see PARA 273 ante.

3 For the meaning of 'contravention' see PARA 249 note 9 ante.

4 For the meaning of 'doctor' see PARA 243 note 9 ante.

- 5 le under the Misuse of Drugs Act 1971 s 13(2): see PARA 273 ante.
- 6 For the meaning of 'practitioner' see PARA 243 note 9 ante.
- 7 As to the meaning 'supplying' see PARA 249 note 5 ante.
- 8 For the meaning of 'controlled drug' see PARA 238 ante.
- 9 As to such tribunals see PARA 276 post.
- 10 Misuse of Drugs Act 1971 s 14(1).
- 11 le under ibid s 13(1), (2): see PARA 273 ante.
- 12 As to the service of notices see PARA 245 ante.
- 13 Misuse of Drugs Act 1971 s 14(3). For these purposes, 'the respondent' means the doctor or practitioner in respect of whom the reference is made: s 14(2).
- 14 le under ibid s 13(1), (2): see PARA 273 ante.
- 15 Ibid s 14(4).
- 16 Ibid s 14(5).
- 17 Ibid s 14(5)(a).
- 18 For the meaning of 'writing' see PARA 265 note 2 ante.
- 19 Misuse of Drugs Act 1971 s 14(5)(b).
- 20 As to such advisory bodies see PARA 277 post.
- 21 Misuse of Drugs Act 1971 s 14(6). The powers referred to are those under s 14(7): see the text to notes 22-25 infra.
- 22 le a direction under ibid s 13(1), (2): see PARA 273 ante.
- 23 Ibid s 14(7)(a).
- 24 Ibid s 14(7)(b). If a case is referred or referred back to a tribunal, the provisions of s 14(2)-(7) apply as if the reference had been under s 14(1); and any finding, recommendation or advice previously made or given must be disregarded: s 14(8).
- 25 Ibid s 14(7)(c).
- 26 le any order or direction under ibid s 14(7): see the text to notes 22-25 supra.
- 27 Ibid s 16(2).
- 28 le a direction under ibid s 14(7): see the text to notes 22-25 supra.
- 29 Ibid s 16(3)(a).
- 30 Ibid s 16(3). Any such direction takes effect when a copy of it is served on the person to whom it applies: s 16(4).

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(4) DIRECTIONS TO PRACTITIONERS AND PHARMACISTS/275. Temporary directions in urgent cases.

275. Temporary directions in urgent cases.

If the Secretary of State¹ considers that there are grounds for giving a direction² prohibiting a practitioner³ from prescribing, administering and supplying⁴, and from authorising the administration and supply of, controlled drugs⁵ on account of his irresponsible conduct, and that the circumstances of the case require such a direction to be given with the minimum of delay, he may give such a direction for a period of six weeks, beginning with the date on which the direction takes effect⁶, specifying such controlled drugs as he thinks fit⁷.

Where the Secretary of State proposes to give such a temporary direction, he must refer the case to a professional panel⁸ constituted for the purpose⁹, which, after affording the respondent¹⁰ an opportunity of appearing before it and being heard by it, must consider the circumstances of the case, so far as known to it, and must report to the Secretary of State whether the information before it appears to it to afford reasonable grounds for thinking that there has been irresponsible conduct by the practitioner¹¹. The Secretary of State may not give a temporary direction unless the panel reports that the information before it appears to it to afford reasonable grounds for so thinking¹². Where a temporary direction is given, the Secretary of State must forthwith refer¹³ the case to a tribunal¹⁴, if he has not already done so¹⁵.

Unless previously cancelled¹⁶, such a direction ceases to have effect on the occurrence of any of certain events¹⁷.

1 As to the Secretary of State see PARA 3 note 3 ante.

2 I.e. a direction under the Misuse of Drugs Act 1971 s 13(2): see PARA 273 ante.

3 For the meaning of 'practitioner' see PARA 243 note 9 ante.

4 As to the meaning 'supplying' see PARA 249 note 5 ante.

5 For the meaning of 'controlled drug' see PARA 238 ante.

6 Misuse of Drugs Act 1971 s 15(5). In certain circumstances the period may be extended: see s 15(6); and note 15 infra. As to when a direction takes effect see note 7 infra.

7 Ibid s 15(1). The Secretary of State must cause a copy of the direction to be served on the person to whom it applies and must cause notice of it to be published in the London, Edinburgh and Belfast Gazettes: s 16(2). As to the service of documents see PARA 245 ante. The Secretary of State may at any time by further direction cancel the direction (s 16(3)(b)) and must similarly serve and publish any such direction (s 16(3)). Any direction under s 13(2) (as applied by s 15(1)) or under s 16(3) takes effect when the copy is so served: s 16(4).

8 As to such panels see PARA 278 post.

9 Misuse of Drugs Act 1971 s 15(2).

10 For these purposes, 'the respondent' means the practitioner in respect of whom the reference is made: *ibid* s 15(3).

11 Ibid s 15(2)(a).

12 Ibid s 15(2)(b).

13 I.e. in accordance with *ibid* s 14(1): see PARA 274 ante.

14 As to such tribunals see PARA 276 post.

15 Misuse of Drugs Act 1971 s 15(4). In these circumstances the Secretary of State may from time to time by notice in writing served on the person to whom the direction applies extend or further extend the period of operation of the direction for a further 28 days, but may not do so without the consent of the tribunal or, if the case has been referred to another tribunal under s 14(7) (see PARA 274 ante), of that other tribunal: s 15(6). A copy of any such notice must be published in the London, Edinburgh and Belfast Gazettes: s 16(2). For the meaning of 'writing' see PARA 265 note 2 ante.

16 le under ibid s 16(3): see note 7 supra.

17 Ibid s 15(7). The events are: (1) the service on the person concerned of a notice under s 14(3) (see PARA 274 ante) (s 15(7)(a)); (2) the service on him of a notice under s 14(5) (see PARA 274 ante) that the Secretary of State does not propose to give a direction under s 13(2) (see PARA 273 ante) (s 15(7)(b)); (3) the service on him of a copy of a direction given under s 14(7) (see PARA 274 ante) (s 15(7)(c)); (4) the making of an order under s 14(7)(c) (see PARA 274 ante) that no further proceedings are to be taken (s 15(7)(d)); (5) the expiration of the period of operation of the temporary direction (s 15(7)(e)).

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(4) DIRECTIONS TO PRACTITIONERS AND PHARMACISTS/276. Tribunals.

276. Tribunals.

A tribunal appointed¹ in connection with directions prohibiting the prescribing, administering and supplying² of controlled drugs³ consists of five persons, of whom one must be a duly qualified lawyer⁴ appointed by the Lord Chancellor to be chairman⁵ and the others must be persons appointed by the Secretary of State⁶ from among members of the respondent's⁷ profession nominated for the purposes of providing members for such tribunals by any of the relevant bodies⁸.

The quorum of a tribunal is the chairman and two other members⁹. Proceedings are held in private unless the respondent requests otherwise and the tribunal accedes to his request¹⁰. Rules of procedure and evidence may be made by the Lord Chancellor¹¹. The tribunal may administer oaths¹² and any party may issue witness summonses¹³. Subject to these provisions, a tribunal may regulate its own procedure¹⁴.

Fees and allowances may be paid to members¹⁵; compensation and allowances may be paid to witnesses¹⁶; and in certain circumstances the respondent's expenses may be paid out of public funds¹⁷.

1 le for the purposes of the Misuse of Drugs Act 1971 s 14: see PARA 274 ante.

2 As to the meaning 'supplying' see PARA 249 note 5 ante.

3 For the meaning of 'controlled drug' see PARA 238 ante. As to such directions see PARA 273 ante.

4 le: (1) a person who has a seven year general qualification, within the meaning of the Courts and Legal Services Act 1990 s 71 (see LEGAL PROFESSIONS vol 65 (2008) PARA 742); (2) an advocate or solicitor in Scotland of at least seven years' standing; or (3) a member of the Bar of Northern Ireland or solicitor of the Supreme Court of Northern Ireland of at least seven years' standing: Misuse of Drugs Act 1971 s 16(1), Sch 3 para 1(1)(a) (amended by the Courts and Legal Services Act 1990 s 71 (2), Sch 10 para 33).

5 Misuse of Drugs Act 1971 Sch 3 para 1(1)(a) (as amended: see note 4 supra). The chairman of a tribunal must vacate his office on the day on which he attains the age of 70 years; but this provision is subject to the Judicial Pensions and Retirement Act 1993 s 26(4)-(6) (power to authorise continuance in office up to the age of 75 years) (see COURTS vol 10 (Reissue) PARA 535): Misuse of Drugs Act 1971 Sch 3 para 1(2A) (added by the Judicial Pensions and Retirement Act 1993 s 26, Sch 6 para 42(2)). As to the Lord Chancellor see CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARA 477 et seq.

6 As to the Secretary of State see PARA 3 note 3 ante.

7 For the meaning of 'the respondent' see PARAS 274 note 13, 275 note 10 ante.

8 Misuse of Drugs Act 1971 Sch 3 para 1(1)(b). The relevant bodies are: (1) where the respondent is a doctor, the General Medical Council, the Royal Colleges of Physicians of London and Edinburgh, the Royal Colleges of Surgeons of England and Edinburgh, the Royal College of Physicians and Surgeons (Glasgow), the Royal College of Obstetricians and Gynaecologists, the Royal College of General Practitioners, the Royal Medico-Psychological Association and the British Medical Association (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARAS 13, 64) (Sch 3 para 1(2)(a)); (2) where he is a dentist, the General Dental Council and the British Dental Association (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 389) (Sch 3 para 1(2)(b)); and (3) where he is a veterinary practitioner or veterinary surgeon, the Royal College of Veterinary Surgeons and the British Veterinary Association (see ANIMALS vol 2 (2008) PARA 1147 et seq) (Sch 3 para 1(2)(c)). For the meanings of 'doctor', 'dentist', 'veterinary practitioner' and 'veterinary surgeon' see PARA 243 note 9 ante.

9 Ibid Sch 3 para 2.

10 Ibid Sch 3 para 3.

11 See *ibid* Sch 3 para 4(1). The power is exercisable by statutory instrument, which is subject to annulment in pursuance of a resolution of either House of Parliament: Sch 3 para 4(3). As to such rules see the Misuse of Drugs Tribunal (England and Wales) Rules 1974, SI 1974/85 (modified by SI 1991/2684). As to the annulment of statutory instruments see STATUTES vol 44(1) (Reissue) PARA 1516.

12 'Oath' includes affirmation and declaration: Interpretation Act 1978 s 5, Sch 1. As to oaths, affirmations and declarations see CIVIL PROCEDURE vol 11 (2009) PARA 1021 *et seq*.

13 See the Misuse of Drugs Act 1971 Sch 3 para 5(1). The Act refers to writs of subpoena ad testificandum and duces tecum, but these are now known as witness summonses: see CIVIL PROCEDURE vol 11 (2009) PARA 1004. No person may be so compelled to give any evidence or produce any document which he could not be compelled to give or produce on the trial of an action: Sch 3 para 5(1). The Supreme Court Act 1981 s 36 (see CIVIL PROCEDURE vol 11 (2009) PARA 1008), which provides procedure for enforcing the attendance of witnesses throughout the United Kingdom, applies: see the Misuse of Drugs Act 1971 Sch 3 para 5(2) (amended by the Supreme Court Act 1981 s 152(1), Sch 5). For the meaning of 'United Kingdom' see PARA 7 note 3 *ante*.

14 Misuse of Drugs Act 1971 Sch 3 para 6. The validity of the proceedings of a tribunal are not affected by any defect in the appointment of a member of the tribunal or by reason of the fact that a person not entitled to do so took part in the proceedings: Sch 3 para 7.

15 See *ibid* Sch 3 para 8. Any expenses incurred by a tribunal with the approval of the Secretary of State must be defrayed by him: Sch 3 para 11. The Secretary of State must make available such accommodation, the services of such officers and such other facilities as he considers appropriate to enable the tribunal to perform its functions: Sch 3 para 12.

16 See *ibid* Sch 3 para 9.

17 See *ibid* Sch 3 para 10.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

276 Tribunals

TEXT AND NOTES--See Constitutional Reform Act 2005 s 19, Sch 7 para 4 (protected functions of the Lord Chancellor) and CONSTITUTIONAL LAW AND HUMAN RIGHTS.

NOTE 4--1971 Act Sch 3 para 1(1)(a) further amended: Tribunals, Courts and Enforcement Act 2007 Sch 10 para 10; Constitutional Reform Act 2005 Sch 11 para 5.

TEXT AND NOTE 5--Any appointment to the office of chairman of a tribunal in exercise of the function under the 1971 Act Sch 3 para 1(1)(a) must be made, by virtue of the Constitutional Reform Act 2005 s 85, Sch 14 Pt 3, in accordance with ss 85-93, 96: see COURTS vol 10 (Reissue) PARA 515B.18.

NOTE 13--Supreme Court Act 1981 now cited as Senior Courts Act 1981: Constitutional Reform Act 2005 Sch 11 para 1 (in force 1 October 2009: SI 2009/1604).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(4) DIRECTIONS TO PRACTITIONERS AND PHARMACISTS/277. Advisory bodies.

277. Advisory bodies.

An advisory body appointed¹ in connection with directions prohibiting the prescribing, administering and supplying² of controlled drugs³, consists of three persons of whom one must be a Queen's Counsel appointed by the Lord Chancellor to be its chairman⁴, another must be appointed by the Secretary of State⁵, being a member of the respondent's⁶ profession who is an officer of a government department⁷, and the other must be appointed by the Secretary of State from among the members of the respondent's profession nominated by the relevant professional body⁸.

The respondent is entitled to appear before and be heard by the advisory body either in person or by counsel or solicitor⁹. Except where otherwise provided, the body may regulate its own procedure¹⁰.

1 le for the purposes of the Misuse of Drugs Act 1971 s 14: see PARA 274 ante.

2 As to the meaning 'supplying' see PARA 249 note 5 ante.

3 For the meaning of 'controlled drug' see PARA 238 ante.

4 Misuse of Drugs Act 1971 s 16(1), Sch 3 para 13(1)(a). The chairman of an advisory body must vacate his office on the day on which he attains the age of 70 years; but this provision is subject to the Judicial Pensions and Retirement Act 1993 s 26(4)-(6) (power to authorise continuance in office up to the age of 75 years) (see COURTS vol 10 (Reissue) PARA 535): Misuse of Drugs Act 1971 Sch 3 para 13(1A) (added by the Judicial Pensions and Retirement Act 1993 s 26, Sch 6 para 42(3)). As to Queen's Counsel see LEGAL PROFESSIONS vol 66 (2009) PARA 1124. As to the Lord Chancellor see CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARA 477 et seq.

5 As to the Secretary of State see PARA 3 note 3 ante.

6 For the meaning of 'the respondent' see PARAS 274 note 13, 275 note 10 ante.

7 Misuse of Drugs Act 1971 Sch 3 para 13(1)(b).

8 Ibid Sch 3 para 13(1)(c). As to the relevant bodies see PARA 276 note 8 ante.

9 Ibid Sch 3 para 14.

10 Ibid Sch 3 para 15. The provisions of Sch 3 paras 3, 7, 8, 10-12 (see PARA 276 ante) apply in relation to an advisory body as they apply in relation to a tribunal: Sch 3 para 16.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(4) DIRECTIONS TO PRACTITIONERS AND PHARMACISTS/278. Professional panels.

278. Professional panels.

A professional panel appointed¹ in connection with a temporary direction prohibiting a practitioner² from prescribing, administering and supplying³, and from authorising the administration and supply of, controlled drugs⁴ consists of a chairman and two other persons appointed by the Secretary of State⁵ from among the members of the respondent's⁶ profession after consulting such one or more of the relevant bodies⁷ as the Secretary of State considers appropriate⁸.

The respondent is entitled to appear before and be heard by the panel either in person or by counsel or solicitor⁹. Except where otherwise provided, a panel may regulate its own procedure¹⁰.

1 le for the purposes of the Misuse of Drugs Act 1971 s 15: see PARA 275 ante.

2 For the meaning of 'practitioner' see PARA 243 note 9 ante.

3 As to the meaning 'supplying' see PARA 249 note 5 ante.

4 For the meaning of 'controlled drug' see PARA 238 ante.

5 As to the Secretary of State see PARA 3 note 3 ante.

6 For the meaning of 'the respondent' see PARAS 274 note 13, 275 note 10 ante.

7 As to the relevant bodies see PARA 276 note 8 ante.

8 Misuse of Drugs Act 1971 s 16 (1), Sch 3 para 17.

9 Ibid Sch 3 para 18.

10 Ibid Sch 3 para 19. The provisions of Sch 3 paras 3, 7, 8 (see PARA 276 ante) apply in relation to a professional panel as they apply in relation to a tribunal: Sch 3 para 20.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(5) ENFORCEMENT AND OFFENCES/279. Powers of entry and inspection.

(5) ENFORCEMENT AND OFFENCES

279. Powers of entry and inspection.

For the purposes of the execution of the Misuse of Drugs Act 1971 and Part II of the Criminal Justice (International Co-operation) Act 1990¹, a constable² or other person authorised by a general or special order of the Secretary of State³ may enter the premises of a person⁴ carrying on business as a producer or supplier⁵ of any controlled drugs⁶ and may demand the production of, and inspect, any books or documents relating to dealings in any such drugs and may inspect stocks of any such drugs⁷. A person commits an offence⁸ if he intentionally obstructs a person in the exercise of his powers under these provisions⁹, or if he conceals from such a person any such books, documents, stocks or drugs¹⁰, or if without reasonable excuse, he fails to produce any such books or documents where their production is demanded by such a person¹¹.

1 The powers conferred by the Misuse of Drugs Act 1971 s 23(1) are exercisable also for the purposes of the execution of the Criminal Justice (International Co-operation) Act 1990 Pt II (ss 12-24) (see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARAS 772-773, 780): Misuse of Drugs Act 1971 s 23(3A) (added by the Criminal Justice (International Co-operation) Act 1990 s 23(1), (4)).

2 As to the office of constable see POLICE vol 36(1) (2007 Reissue) PARA 101 et seq.

3 As to the Secretary of State see PARA 3 note 3 ante.

4 For the meaning of 'person' see PARA 21 note 7 ante.

5 As to the meaning 'supplying' see PARA 249 note 5 ante.

6 For the meaning of 'controlled drug' see PARA 238 ante.

7 Misuse of Drugs Act 1971 s 23(1).

8 The penalty for such an offence on summary conviction is imprisonment for a term not exceeding six months or a fine not exceeding the prescribed sum or both, and on conviction on indictment is imprisonment for a term not exceeding two years or a fine or both: *ibid* s 25(1), (2), Sch 4 (amended by virtue of the Magistrates' Courts Act 1980 s 32(2)). As to the prescribed sum see PARA 32 note 3 ante.

9 Misuse of Drugs Act 1971 s 23(4)(a).

10 *Ibid* s 23 (4)(b).

11 *Ibid* s 23(4)(c). The burden of proving reasonable excuse rests on the accused: s 23(4)(c). As to the standard of proof see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(3) (2006 Reissue) PARA 1372.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(5) ENFORCEMENT AND OFFENCES/280. Powers of search and seizure.

280. Powers of search and seizure.

If a constable¹ has reasonable grounds to suspect that any person is in possession² of a controlled drug³ in contravention of the Misuse of Drugs Act 1971 or regulations made under the Act, he may search him, and detain him for that purpose⁴; search any vehicle or vessel⁵ in which the constable suspects the drug may be found, and for that purpose require the person in control of the vehicle or vessel to stop it⁶; and seize and detain, for the purposes of proceedings under the Act, anything found in the course of the search which appears to him to be evidence of an offence⁷.

If a justice of the peace⁸ is satisfied by information on oath⁹ that there is reasonable ground for suspecting:

- 260 (1) that any controlled drugs are, in contravention of the Act or of any regulations made thereunder, in the possession of a person on any premises¹⁰; or
- 261 (2) that a document directly or indirectly relating to, or connected with, a transaction or dealing which was, or an intended transaction or dealing which would if carried out be, an offence under the Act, or in the case of a transaction or dealing carried out or intended to be carried out in a place outside the United Kingdom¹¹, an offence against the provisions of a corresponding law¹² in force in that place, is in the possession of a person on any premises¹³,

he may grant a warrant authorising any constable acting for the police area in which the premises are situated, at any time or times within one month¹⁴ from the date of the warrant, to enter, if need be by force, the premises named in the warrant, and to search the premises and any persons found therein and, if there is reasonable ground for suspecting that an offence under the Act has been committed in relation to any controlled drugs found on the premises or in the possession of any such persons, or that a document so found is such a document as is mentioned in head (2) above, to seize and detain those drugs or that document, as the case may be¹⁵.

It is an offence intentionally to obstruct a person in the exercise of his powers under these provisions¹⁶.

1 As to the office of constable see POLICE vol 36(1) (2007 Reissue) PARA 101 et seq.

2 As to references to possession see PARA 252 note 7 ante.

3 For the meaning of 'controlled drug' see PARA 238 ante.

4 Misuse of Drugs Act 1971 s 23(2)(a). This power does not, however, authorise a search by a constable of a person in police detention at a police station or an intimate search of a person by a constable: see the Police and Criminal Evidence Act 1984 s 53(1); and CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARA 1006. See also note 7 infra.

5 'Vessel' includes a hovercraft within the meaning of the Hovercraft Act 1968 (see SHIPPING AND MARITIME LAW vol 93 (2008) PARA 381); Misuse of Drugs Act 1971 s 23(2).

6 Ibid s 23(2)(b). See also note 7 infra.

7 Ibid s 23(2)(c). Nothing in s 23(2) prejudices any power of search or any power to seize or detain property exercisable by a constable apart from that provision: s 23(2). The powers of seizure conferred by s 23(2), (3)

are powers of seizure to which the Criminal Justice and Police Act 2001 ss 50, 51 (additional powers of seizure) apply: see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARAS 890-891.

8 As to justices of the peace see MAGISTRATES vol 29(2) (Reissue) PARA 501 et seq.

9 For the meaning of 'oath' see PARA 276 note 12 ante.

10 Misuse of Drugs Act 1971 s 23(3)(a).

11 For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

12 For the meaning of 'corresponding law' see PARA 260 note 15 ante.

13 Misuse of Drugs Act 1971 s 23(3)(b).

14 For the meaning of 'month' see PARA 22 note 15 ante.

15 Misuse of Drugs Act 1971 s 23(3). See also note 7 supra. The warrant does not authorise a constable to seize and detain items subject to legal privilege, excluded material, or special procedure material consisting of documents or records other than documents: see the Police and Criminal Evidence Act 1984 s 9(2); and CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARA 874. With the exception of head (1) in the text, the Misuse of Drugs Act 1971 s 23 also applies to offences under the Criminal Justice (International Co-operation) Act 1990 ss 12, 13 (see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARA 773), save that references to 'controlled drugs' should be read as references to 'scheduled substances' within the meaning of that Act: Misuse of Drugs Act 1971 s 23(3A) (added by the Criminal Justice (International Co-operation) Act 1990 s 23(1), (4)). It is not necessary for the justices to keep a record of proceedings relating to the grant of a warrant unless information is elicited which is not contained in the body of the information: *R (on the application of Cronin) v Sheffield Justices* [2002] EWHC 2568 (Admin), [2003] 1 WLR 752, DC. If the justice has acted properly in terms of the Misuse of Drugs Act 1971 s 23(3), the grant of a warrant does not breach the Convention for the Protection of Human Rights and Fundamental Freedoms (1950) art 8 (right to respect for private and family life: see CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARA 149): *Birse v HM Advocate* (2000) Times, 28 June, 2000 SLT 869; sub nom *Birse v MacNeill* 2000 JC 503.

16 Misuse of Drugs Act 1971 s 23(4)(a). The penalty for such an offence on summary conviction is imprisonment for a term not exceeding six months or a fine not exceeding the prescribed sum or both, and on conviction on indictment is imprisonment for a term not exceeding two years or a fine or both: s 25(1), (2), Sch 4 (amended by virtue of the Magistrates' Courts Act 1980 s 32(2)). As to the prescribed sum see PARA 32 note 3 ante. The obstruction must be intentional, and the person being detained must know that the constable is detaining him or wishing to detain him for the purpose of searching for illicit drugs: *R v Forde* (1985) 81 Cr App Rep 19, CA. Obstruction is not limited to physical personal obstruction or restraint: *Carmichael v Brannan* 1986 SLT 5. See also *DPP v Meaden* [2003] EWHC 3005 (Admin), [2004] 4 All ER 75 (the Misuse of Drugs Act 1971 s 23 authorises police officers to restrict the movement of persons to one room, by using no more force than is necessary, while another room is being searched).

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(5) ENFORCEMENT AND OFFENCES/281. Powers of arrest.

281. Powers of arrest.

A number of offences under the Misuse of Drugs Act¹ are arrestable offences², to which powers of summary arrest apply³. A constable who has reasonable grounds for suspecting that an arrestable offence has been committed may arrest without a warrant anyone whom he has reasonable grounds for suspecting to be guilty of the offence, and also anyone who is about to commit an arrestable offence or anyone whom he has reasonable grounds for suspecting to be about to commit an arrestable offence⁴. Any person may arrest without a warrant anyone who is in the act of committing an arrestable offence or anyone whom he has reasonable grounds for suspecting to be committing an arrestable offence or, where an arrestable offence has been committed, may arrest without a warrant anyone who is guilty of the offence or anyone whom he has reasonable grounds for suspecting to be guilty of it⁵. Offences for which a person may be arrested under the Customs and Excise Management Act 1979 are also arrestable offences⁶. Certain drug trafficking offences are serious arrestable offences, to which additional police powers apply⁷.

1 See the offences under the Misuse of Drugs Act 1971 s 4(2), (3) (see PARA 249 ante), s 5(2), (3) (see PARA 252 ante), s 6(2) (see PARA 254 ante), s 8 (see PARA 255 ante), s 9 (see PARA 257 ante), s 12(6) (see PARA 272 ante), s 13(3) (see PARA 273 ante), and s 20 (see PARA 260 ante).

2 A constable may arrest any person who he has reasonable grounds for suspecting has committed an offence: see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARA 924. As to powers of arrest generally see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARA 910 et seq.

3 See the Police and Criminal Evidence Act 1984 s 24(1), (2) (s 24(1) amended by the Criminal Justice and Court Services Act 2000 s 74, Sch 7 Pt II paras 76, 77; and by the Police Reform Act 2002 s 48(1), (2); and the Police and Criminal Evidence Act 1984 s 24(2) substituted by the Police Reform Act 2002 s 48(1), (3)); and the Police and Criminal Evidence Act 1984 Sch 1A para 6A (Sch 1A added by the Police Reform Act 2002 s 48(1), (5), Sch 6; and the Police and Criminal Evidence Act 1984 Sch 1A para 6A added by the Criminal Justice Act 2003 s 3(1), (3)). The Police and Criminal Evidence Act 1984 Sch 1A (as added and amended) is repealed as from a day to be appointed by the Serious Organised Crime and Police Act 2005 ss 111, 174(2), Sch 7 Pt 1 para 24(1), (3), Sch 17 Pt 2. At the date at which this volume states the law, no such day had been appointed.

The powers of summary arrest also apply to conspiring to commit an offence under the Misuse of Drugs Act 1971 s 5(2), attempting to commit any such offence, and inciting, aiding, abetting, counselling or procuring the commission of any such offence: see the Police and Criminal Evidence Act 1984 s 24(3) (amended by the Police Reform Act 2002 s 48(1), (4)(a)).

As from a day to be appointed, the powers of arrest referred to in the Police and Criminal Evidence Act 1984 s 24 (as amended) are replaced by new powers of arrest without a warrant: see ss 24, 24A (s 24 prospectively substituted, and s 24A prospectively added, by the Serious Organised Crime and Police Act 2005 s 110(1)); and CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARAS 924-925. At the date at which this volume states the law, no such day had been appointed.

4 See the Police and Criminal Evidence Act 1984 s 24(6), (7). See also note 3 supra.

5 See *ibid* s 24(4), (5). See also note 3 supra.

6 See *ibid* s 24(2) (as substituted: see note 3 supra); Sch 1A para 1 (as added; prospectively repealed: see note 3 supra). See also note 3 supra. The following offences under the Customs and Excise Management Act 1979 are arrestable offences: improper importation of goods contrary to s 50(3) (as amended) (see CUSTOMS AND EXCISE vol 12(3) (2007 Reissue) PARA 994), improper exportation of goods contrary to s 68(3) (as amended) (see CUSTOMS AND EXCISE vol 12(3) (2007 Reissue) PARA 1029), and fraudulent evasion of duty under s 170(2) (as amended) (see CUSTOMS AND EXCISE vol 12(3) (2007 Reissue) PARA 1178). As to such offences in relation to controlled drugs see PARA 248 note 3 ante.

7 See the Police and Criminal Evidence Act 1984 s 116(1), (2)(c) (substituted by the Proceeds of Crime Act 2002 s 456, Sch 11 paras 1, 14(1), (4)). As from a day to be appointed, the provisions of the Police and Criminal Evidence Act 1984 s 116 (as substituted) are repealed by the Serious Organised Crime and Police Act 2005 Sch 7 Pt 3 para 43(1), (12), Sch 17 Pt 2. At the date at which this volume states the law, no such day had been appointed.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

281 Powers of arrest

NOTE 3--Day now appointed: SI 2005/3495.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(5) ENFORCEMENT AND OFFENCES/282. Offences.

282. Offences.

It is an offence under the Misuse of Drugs Act 1971 unlawfully to produce or be concerned in the production of a controlled drug¹; to supply or offer to supply such a drug or to be concerned in the doing of either activity by another²; to have possession of a controlled drug³ or to have such possession with intent to supply it to another⁴; to cultivate cannabis plants⁵; to be the occupier of or to be concerned in the management of premises and to permit or suffer certain activities there⁶; to smoke or otherwise use prepared opium, or frequent a place used for that purpose or have possession of utensils used for that purpose⁷; to supply or offer to supply articles which may be used for administering drugs⁸; to contravene regulations⁹ or the terms of a licence or authority¹⁰; to give false information¹¹; to assist in or induce the commission abroad of an offence under a corresponding law¹²; to contravene directions as to safe custody¹³; to fail to comply with a notice requiring information as to prescriptions and other matters¹⁴ or to give false information under such a notice¹⁵; to contravene certain directions¹⁶; to obstruct powers of entry¹⁷, and search and seizure¹⁸ or to incite another to commit any such offence¹⁹.

A magistrates' court may try an information for any such offence if the information was laid at any time within 12 months from the commission of the offence²⁰.

1 See the Misuse of Drugs Act 1971 s 4(2); and PARA 249 ante. For the meaning of 'controlled drug' see PARA 238 ante.

2 See *ibid* s 4(3); and PARA 249 ante.

3 See *ibid* s 5(2); and PARA 252 ante.

4 See *ibid* s 5(3); and PARA 252 ante.

5 See *ibid* s 6(2); and PARA 254 ante.

6 See *ibid* s 8; and PARA 255 ante.

7 See *ibid* s 9; and PARA 257 ante.

8 See *ibid* s 9A (as added); and PARA 258 ante.

9 See *ibid* s 18(1); and PARA 260 ante.

10 See *ibid* s 18(2); and PARA 260 ante.

11 See *ibid* s 18(3), (4); and PARA 260 ante.

12 See *ibid* s 20; and PARA 260 ante.

13 See *ibid* s 11(2); and PARA 265 ante.

14 See *ibid* s 17(3); and PARA 268 ante.

15 See *ibid* s 17(4); and PARA 268 ante.

16 See *ibid* ss 12(6), 13(3); and PARAS 272-273 ante.

17 See *ibid* s 23(4); and PARA 279 ante.

18 See *ibid* s 23(4); and PARA 280 ante.

19 See *ibid* s 19; and PARA 260 ante.

20 *Ibid* s 25(4) (amended by the Magistrates' Courts Act 1980 s 154, Sch 7 para 103). This provision is expressed to apply notwithstanding anything in the Magistrates' Courts Act 1980 s 127(1) (general limitation of six months): see *MAGISTRATES* vol 29(2) (Reissue) PARA 589.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(5) ENFORCEMENT AND OFFENCES/283. Forfeiture.

283. Forfeiture.

The court by or before which a person¹ is convicted of an offence under the Misuse of Drugs Act 1971, or of a drug trafficking offence², may order anything³ shown to the satisfaction of the court to relate to the offence to be forfeited and either destroyed or dealt with in such other manner as the court may order⁴. However, the court must not order anything to be forfeited where a person claiming to be the owner of or otherwise interested in it applies to be heard by the court, unless an opportunity has been given to him to show cause why the order should not be made⁵.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 Ie an offence which is specified in the Proceeds of Crime Act 2002 Sch 2 para 1, or so far as it relates to that provision, Sch 2 para 10: Misuse of Drugs Act 1971 s 27(3) (added by the Proceeds of Crime Act 2002 s 456, Sch 11 paras 1, 5(1), (3)). As to such offences see SENTENCING AND DISPOSITION OF OFFENDERS vol 92 (2010) PARA 393.

3 'Anything' refers to tangible things of which physical possession can be taken by a person authorised to do so and which are capable of being physically destroyed by that person or disposed of by him in some other way: *R v Cuthbertson* [1981] AC 470, [1980] 2 All ER 401, HL. It does not include real property: *R v Beard* [1974] 1 WLR 1549; *R v Khan*, *R v Crawley* [1982] 3 All ER 969, [1982] 1 WLR 1405, CA.

4 Misuse of Drugs Act 1971 s 27(1) (amended by the Criminal Justice Act 1988 s 70; and the Proceeds of Crime Act 2002 s 456 Sch 11 paras 1, 5(1), (2)). The court must adopt a judicial and not a whimsical approach in determining how anything is to be dealt with: *R v Beard* [1974] 1 WLR 1549; *R v Glover* (1974) (unreported). To come within the forfeiture provisions under the Misuse of Drugs Act 1971, the offence has to be one which has been expressly created by the Act: *R v Cuthbertson* [1981] AC 470, [1980] 2 All ER 401, HL (appellants had been convicted of conspiracy to contravene the Misuse of Drugs Act 1971 s 4, but successfully argued that conspiracy to commit an offence under the Act was not an offence expressly created by the Act, and the court therefore had no jurisdiction to order forfeiture under s 27). As to the confiscation of the proceeds of crime see the Proceeds of Crime Act 2002 s 13; and SENTENCING AND DISPOSITION OF OFFENDERS vol 92 (2010) PARA 400.

5 Misuse of Drugs Act 1971 s 27(2). The defendant must also be given an opportunity to call evidence to establish that these requirements have not been met, before a forfeiture order is made: *R v Churcher* (1986) 8 Cr App Rep (S) 94, CA.

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/3. CONTROLLED DRUGS/(5) ENFORCEMENT AND OFFENCES/283A. Supervision of management and use of controlled drugs.

283A. Supervision of management and use of controlled drugs.

1. Accountable officers and their responsibilities as to controlled drugs

The relevant authority¹ may by regulations make provision for or in connection with requiring designated bodies² to nominate or appoint persons who are to have prescribed responsibilities in relation to the safe, appropriate and effective management and use of controlled drugs³ in connection with (1) activities carried on by or on behalf of the designated bodies, and (2) activities carried on by or on behalf of bodies or persons providing services under arrangements made with the designated bodies⁴. The person who is to be so nominated or appointed by a designated body is to be known as its accountable officer⁵. The descriptions of bodies, or bodies, that may be so prescribed are descriptions of bodies, or bodies, appearing to the relevant authority (a) to be directly or indirectly concerned with the provision of health care⁶ (whether or not for the purposes of the health service⁷), or (b) to be otherwise carrying on activities that involve, or may involve, the supply or administration of controlled drugs⁸. Regulations under these provisions may make provision (i) for conditions that must be satisfied in relation to a person if he is to be nominated or appointed by a designated body as the body's accountable officer; (ii) for a single person to be nominated or appointed as the accountable officer for each of two or more designated bodies where those bodies are satisfied as to the prescribed matters; (iii) requiring a designated body that has an accountable officer to provide the officer with funds and other resources necessary for enabling the officer to discharge his responsibilities as accountable officer for the body; (iv) for ensuring that an accountable officer, in discharging his responsibilities, has regard to best practice in relation to the use of controlled drugs; (v) for the persons required to be nominated or appointed⁹ to be known by such name as is prescribed; (vi) for making such amendments of any enactment¹⁰ as appear to the relevant authority to be required in connection with any provision made in pursuance of head (v) above; (vii) for creating offences punishable on summary conviction by a fine not exceeding level 5 on the standard scale¹¹ or for creating other procedures for enforcing any provisions of the regulations¹². The responsibilities that may be imposed on a designated body's accountable officer by regulations under these provisions include responsibilities as to the establishment and operation of arrangements for (A) securing the safe management and use of controlled drugs; (B) monitoring and auditing the management and use of such drugs; (C) ensuring that relevant individuals receive appropriate training and that their training needs are regularly reviewed; (D) monitoring and assessing the performance of such individuals in connection with the management or use of such drugs; (E) making periodic inspections of premises used in connection with the management or use of such drugs; (F) recording, assessing and investigating concerns expressed about incidents that may have involved improper management or use of such drugs; (G) ensuring that appropriate action is taken for the purpose of protecting patients or members of the public in cases where such concerns appear to be well-founded; (H) where required by regulations¹³ the sharing of information¹⁴. A designated body may confer on its accountable officer such powers as it thinks appropriate to enable him to discharge any of the responsibilities imposed on him as accountable officer for the body by regulations under the above provisions¹⁵.

¹ In the Health Act 2006 Pt 3 Ch 1 (ss 17-25) 'relevant authority' is to be read in accordance with s 24 (see PARA 283A.7): s 25(1).

2 In ibid Pt 3 Ch 1 'designated body' means (1) a body falling within any description of bodies prescribed as designated bodies for the purposes of s 17, or (2) a body prescribed as a designated body for those purposes: s 17(3). 'Body' includes an unincorporated association: s 25(1). In s 17 'prescribed' means prescribed by regulations under s 17: s 17(11).

3 In ibid Pt 3 Ch 1 'controlled drug' has the meaning given by the Misuse of Drugs Act 1971 s 2 (see PARA 238): Health Act 2006 s 25(1). Any reference to the management or use of controlled drugs includes (1) the storage, carriage and safe custody of such drugs, (2) the prescribing and supply of such drugs, (3) the administration of such drugs, (4) the recovery of such drugs when no longer needed, and (5) the disposal of such drugs: s 25(2).

4 Ibid s 17(1). See the Controlled Drugs (Supervision of Management and Use) Regulations 2006, SI 2006/3148 (amended by SI 2007/3101, SI 2009/462) and the Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008, SI 2008/3239 (amended by SI 2009/1824). As to regulations under the Health Act 2006 generally see s 79. See further NOTE 14.

5 Ibid s 17(2). This is subject to any regulations made by virtue of s 17(5)(e) (see head (v) in the text): s 17(2).

6 In ibid Pt 3 Ch 1 'health care' means (1) services provided to individuals for or in connection with the prevention, diagnosis or treatment of illness, and (2) the promotion and protection of public health: s 25(1). 'Illness' in relation to England and Wales, has the meaning given by the National Health Service Act 2006 s 275: Health Act 2006 s 25(1) (amended by National Health Service (Consequential Provisions) Act 2006 Sch 1 para 282(b)).

7 In the Health Act 2006 'the health service', in relation to England and Wales, has the same meaning as in the National Health Service Act 2006: Health Act 2006 s 82(1) (amended by National Health Service (Consequential Provisions) Act 2006 Sch 1 para 290(c)).

8 Health Act 2006 s 17(4).

9 As mentioned in ibid s 17(1).

10 In the Health Act 2006 'enactment' includes any provision of subordinate legislation (within the meaning of the Interpretation Act 1978), and references to enactments include enactments passed or made after the passing of the Health Act 2006 (ie 19 July 2006): s 82(2). Section 82(2) applies except where the context otherwise requires: s 82(3).

11 As to the standard scale see PARA 6.

12 Health Act 2006 s 17(5). See further NOTE 14.

13 Ie under ibid s 18 (see PARA 283A.2).

14 Ibid s 17(6). The arrangements mentioned in s 17(6) may be arrangements established (according to the circumstances) (1) by the accountable officer, (2) by the designated body (or any of the designated bodies) for which he is the accountable officer, or (3) by a body or person acting on behalf of, or providing services under arrangements made with, the designated body (or any of the designated bodies): s 17(7). In s 17(6) (a) references to the management or use of controlled drugs are to the management or use of drugs in connection with activities carried on by a body or person within head (2) or (3), and (b) 'relevant individual' means an individual who, whether as (i) a health care professional, or (ii) an employee who is not a health care professional, or (iii) otherwise, is engaged in any activity carried on by a body or person within head (2) or (3) that involves, or may involve, the management or use of controlled drugs: s 17(8). 'Health care professional', in relation to England and Wales, has the meaning given by the National Health Service Act 2006 s 91(2)(a): Health Act 2006 s 25(1) (amended by National Health Service (Consequential Provisions) Act 2006 Sch 1 para 282(a)).

Nothing in the Health Act 2006 s 17(5)-(7) is to be read as prejudicing the generality of s 17(1): s 17(10).

15 Ibid s 17(9).

2. Co-operation between health bodies and other organisations

The relevant authority¹ may by regulations make provision for or in connection with requiring responsible bodies² to co-operate with each other in connection with (1) the identification of cases in which action may need to be taken in respect of matters arising in relation to the management or use of controlled drugs by relevant persons³; (2) the consideration of issues

relating to the taking of action in respect of such matters; (3) the taking of action in respect of such matters⁴. Regulations under these provisions may make provision (a) for requiring a responsible body to disclose information to any other such body or bodies in prescribed circumstances, or in circumstances where it appears to the responsible body that the prescribed conditions are satisfied, whether or not the disclosure of information has been requested; (b) in relation to a responsible body which has an accountable officer⁵, for requiring disclosures to be made by or to that officer instead of by or to the body; (c) in relation to a responsible body which is a police force, for imposing duties on the chief officer⁶; (d) for requiring a responsible body, in prescribed circumstances, to consult the prescribed accountable officer in connection with any requirement imposed on the body under the regulations; (e) for imposing duties on accountable officers in relation to the taking of action for the purpose of protecting the safety of patients or the general public⁷.

1 In the Health Act 2006 Pt 3 Ch 1 (ss 17-25) 'relevant authority' is to be read in accordance with s 24 (see PARA 283A.7): s 25(1).

2 In *ibid* Pt 3 Ch 1 'responsible body' means (1) a body falling within any description of bodies prescribed as responsible bodies for the purposes of s 18, or (2) a body prescribed as a responsible body for those purposes: s 18(2). For the meaning of 'body' see PARA 283A.1. In s 18 'prescribed' means prescribed by regulations under s 18: s 18(9)(c). The descriptions of bodies, or bodies, that may be so prescribed are (a) descriptions of bodies, or bodies, which fall within s 18(4); and (b) police forces: s 18(3). Descriptions of bodies, or bodies, fall within s 18(4) if they appear to the relevant authority (i) to be directly or indirectly concerned with the provision of health care (whether or not for the purposes of the health service), (ii) to be otherwise carrying on activities that involve, or may involve, the supply or administration of controlled drugs, (iii) to have powers of inspection in relation to the management or use of controlled drugs, (iv) to be public or local authorities with responsibilities in relation to social care, or (v) to be public or local authorities (not within heads (i)-(iv)) whose responsibilities include responsibilities with respect to matters such as are mentioned in s 18(1): s 18(4). For the meaning of 'health care' and 'health service' see PARA 283A.1. For the meaning of 'controlled drug' and 'management or use of controlled drugs' see PARA 283A.1. In s 18 'police force' means a police force in England or Wales: s 18(9)(b).

3 In *ibid* s 18 'relevant person' means (1) a person falling within any description of persons prescribed as relevant persons for the purposes of s 18, or (2) an individual to whom s 19(3) applies: s 19(1). In s 19 'prescribed' means prescribed by regulations under s 18: s 19(4). The descriptions of persons that may be prescribed for the purposes of s 18 are descriptions of persons appearing to the relevant authority to be carrying on, or engaged in, activities that involve, or may involve, the supply or administration of controlled drugs: s 19(2). Section 19(3) applies to an individual who, whether as (a) a health care professional, or (b) an employee who is not a health care professional, or (c) otherwise, is engaged in any activity carried on by a designated body, or by a body or person acting on behalf of, or providing services under arrangements made with, a designated body that involves, or may involve, the management or use of controlled drugs: s 19(3). For the meaning of 'health care professional' and 'designated body' see PARA 283A.1.

4 *Ibid* s 18(1). See the Controlled Drugs (Supervision of Management and Use) Regulations 2006, SI 2006/3148 (amended by SI 2007/3101); the Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008, SI 2008/3239; and PARA 283A.1. As to regulations under the Health Act 2006 generally see s 79. See further NOTE 7.

5 In *ibid* Pt 3 Ch 1 'accountable officer' is to be read in accordance with s 17(2) (see PARA 283A.1): s 25(1).

6 In *ibid* s 18 'chief officer' means, in relation to a police force in England and Wales, the chief officer of police: s 18(9)(a).

7 *Ibid* s 18(5). The duties that may be imposed on an accountable officer in pursuance of head (e) in the TEXT include a duty to make recommendations to a responsible body as to any action which the officer considers that the body should take for the purpose mentioned in that head: s 18(6). The action that may be so recommended includes action in relation to the institution of disciplinary proceedings: s 18(7).

Nothing in s 18(5)-(7) is to be read as prejudicing the generality of s 18(1): s 18(8).

3. Controlled drugs: power to enter and inspect

A constable or an authorised person¹ may, for the purpose of securing the safe, appropriate and effective management and use of controlled drugs² (1) enter any relevant premises³; (2)

inspect any precautions taken on the premises for the safe custody of controlled drugs; (3) inspect any stocks of controlled drugs kept on the premises; (4) require any relevant records⁴ kept on the premises to be produced for his inspection⁵.

1 In the Health Act 2006 s 20 'authorised person' means (subject to s 20(6)) (1) a person authorised by the relevant authority, (2) an accountable officer, or (3) where a designated body is required by regulations under s 17 (see PARA 283A.1) to nominate or appoint an accountable officer, a member of the staff of the designated body authorised by it: s 20(5). As to 'relevant authorities' see PARA 283A.7. For the meaning of 'accountable officer' and 'designated body' see PARA 283A.1. Authorisations given under s 20(5) may be general or specific: s 20(5).

The accountable officer of a designated body specified, or of a description specified, in directions given by the relevant authority is not an authorised person for the purposes of s 20; and such a designated body may not authorise members of its staff under head (3): s 20(6). Directions under s 20(6) are to be given by regulations or in writing; but any such directions which relate to more than one designated body are to be given by regulations: s 20(10). Directions under s 20(6) given in writing may be varied or revoked by subsequent directions under s 20(6): s 20(11).

2 For the meaning of 'controlled drug' and 'management or use of controlled drugs' see PARA 283A.1.

3 The relevant authority may by regulations prescribe descriptions of premises which are to be 'relevant premises' for the purposes of the Health Act 2006 s 20 in relation to constables and authorised persons of descriptions prescribed in the regulations: s 20(7). See the Controlled Drugs (Supervision of Management and Use) Regulations 2006, SI 2006/3148 (amended by SI 2007/3101); the Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008, SI 2008/3239; and PARA 283A.1. As to regulations under the Health Act 2006 generally see s 79. The descriptions of premises that may be so prescribed are descriptions of premises (or parts thereof) appearing to the relevant authority to be used in connection with (1) the provision of health care (whether or not for the purposes of the health service), or (2) the supply or administration of controlled drugs: s 20(8). For the meaning of 'health care' and 'health service' see PARA 283A.1.

4 In *ibid* Pt 3 Ch 1 (ss 17-25) 'relevant records' means records kept with respect to controlled drugs in pursuance of regulations under the Misuse of Drugs Act 1971 s 10 (see PARA 263): Health Act 2006 s 20(9).

5 *Ibid* s 20(1). The powers conferred by s 20(1) may be exercised only (1) at a reasonable hour, and (2) on production (if required) of the written authority of the person exercising them: s 20(2). The power conferred by head (1) in the TEXT may be exercised by an authorised person to enter relevant premises which are or form part of a private dwelling only if he is accompanied by a constable: s 20(3). But s 20(3) does not apply in such circumstances as may be prescribed by regulations made by the relevant authority: s 20(3). See SI 2006/3148; SI 2008/3239, NOTE 3. The power conferred by head (4) in the TEXT includes power (a) to take copies of or extracts from relevant records, and (b) to take possession of any relevant records kept on the premises and retain them for so long as the person exercising the power considers necessary: Health Act 2006 s 20(4).

4. Offences in connection with power to enter and inspect

A person commits an offence if he (1) intentionally obstructs a person in the exercise of his powers to enter and inspect¹, (2) conceals from a person² anything which that person is entitled to inspect, or (3) without reasonable excuse fails to produce any relevant records³ which a person⁴ requires to be produced⁵. A person guilty of such an offence is liable (a) on conviction on indictment, to imprisonment for a term not exceeding two years or to a fine, or to both; (b) on summary conviction, to imprisonment for a term not exceeding 12 months or to a fine not exceeding the statutory maximum⁶, or to both⁷.

1 *Ie* under the Health Act 2006 s 20(1) (see PARA 283A.3).

2 *Ie* a person acting under *ibid* s 20(1).

3 In *ibid* Pt 3 Ch 1 (ss 17-25) 'relevant records' has the meaning given by s 20(9) (see PARA 283A.3): s 25(1).

4 *Ie* a person acting under *ibid* s 20(1).

5 *Ibid* s 21(1).

6 As to the statutory maximum see PARA 32.

⁷ Health Act 2006 s 21(2). For transitional modification see s 78(2) (s 78 partly in force: SI 2007/204, SI 2008/3171 (Wales), SI 2008/1147 (England)).

As to offences committed by bodies corporate, partnerships and other unincorporated associations, see 2006 Act ss 76, 77 (ss 76, 77 partly in force: SI 2007/204, SI 2008/3171 (Wales), SI 2007/1375, SI 2008/1147 (England)).

5. Guidance

The relevant authority¹ may issue guidance to designated bodies² in connection with (1) determining whether conditions specified in regulations³ have been satisfied in relation to the nomination or appointment of a person as a designated body's accountable officer⁴; (2) the discharge by a designated body's accountable officer of any responsibilities imposed on him by regulations⁵; (3) the exercise by designated bodies of their powers relating to accountable officers and their responsibilities⁶; (4) the exercise by designated bodies of their powers relating to power to enter and inspect⁷. The relevant authority may issue guidance to responsible bodies⁸ in connection with their discharge of any duties imposed on them by regulations⁹. Guidance under these provisions may make different provision for different cases or circumstances¹⁰. Designated bodies and responsible bodies must have regard to any guidance under these provisions in exercising any functions to which the guidance relates¹¹.

¹ As to 'relevant authorities' see PARA 283A.7.

² For the meaning of 'designated body' see PARA 283A.1.

³ Ie under the Health Act 2006 s 17 (see PARA 283A.1).

⁴ For the meaning of 'accountable officer' see PARA 283A.1.

⁵ Ie under the Health Act 2006 s 17.

⁶ Ie under ibid s 17(9).

⁷ Ie under ibid s 20(5)(c) (see PARA 283A.3): s 22(1).

⁸ In ibid Pt 3 Ch 1 (ss 17-25) 'responsible body' has the meaning given by s 18(2) (see PARA 283A.2): s 25(1).

⁹ Ie under ibid s 18 (see PARA 283A.2): s 22(2).

¹⁰ Ibid s 22(3).

¹¹ Ibid s 22(4).

6. Crown application

Chapter 1 of Part 3 of the Health Act 2006¹ binds the Crown². No contravention by the Crown of any provision of Chapter 1 of Part 3 of the Health Act 2006 will make the Crown criminally liable; but the High Court may declare unlawful any act or omission of the Crown which constitutes such a contravention³. The provisions of Chapter 1 of Part 3 of the Health Act 2006 apply to persons in the public service of the Crown as they apply to other persons⁴.

¹ Ie the Health Act 2006 ss 17-25.

² Ibid s 23(1).

³ Ibid s 23(2).

⁴ Ibid s 23(3).

7. Relevant authorities

The following provisions¹ apply to functions conferred on the relevant authority by Chapter 1 of Part 3 of the Health Act 2006². Any functions to which these provisions apply are exercisable in relation to England by the Secretary of State³. Any functions to which these provisions apply are exercisable in relation to Wales by the National Assembly for Wales⁴. Any power of the relevant authority to make regulations under Chapter 1 of Part 3 of the Health Act 2006 is exercisable in relation to cross-border bodies⁵ by the Secretary of State after consultation with the Assembly⁶.

1 Ie the Health Act 2006 s 24.

2 Ie *ibid* ss 17-25: s 24(1).

3 Ibid s 24(2). Section 24(2) is subject to s 24(4): s 24(2).

4 Ibid s 24(3). Section 24(3) is subject to s 24(4): s 24(3).

5 A 'cross-border body' is a body which (1) performs (and only performs) functions in respect of England and Wales, and (2) does not perform functions mainly in respect of England or mainly in respect of Wales: *ibid* s 24(5).

6 Ibid s 24(4).

UPDATE

237-283 Controlled Drugs

The Health Act 2006 Pt 3 Ch 1 (ss 17-25) contains provisions relating to the supervision of management and use of controlled drugs. See further PARA 283A.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(1) THE CONTROL OF POISONS/284. Introduction.

4. POISONS

(1) THE CONTROL OF POISONS

284. Introduction.

The law relating to the control of poisons¹ is contained principally in the Poisons Act 1972² and in the Poisons Rules made under that Act³. Under this statutory scheme of control the poisons included in the Poisons List are subject to detailed controls covering their sale, supply, labelling, transport, storage and the containers in which they must be sold⁴.

1 Ie the poisons included in the Poisons List (see PARA 286-288 post). For the meaning of the word 'poison' in another context see *R v Cramp* (1880) 5 QBD 307 (administration of poisons or noxious substances with intent to procure abortion); and CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(1) (2006 Reissue) PARA 110. As to offences relating to the administration of drugs and poisons generally see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(1) (2006 Reissue) PARAS 122-124. As to the sale and use of poisoned grain and bait see ANIMALS vol 2 (2008) PARA 864; and as to the administration of a poisonous or injurious drug to an animal see ANIMALS vol 2 (2008) PARA 864. As to the protection of agricultural workers against risks from hazardous substances see AGRICULTURAL PRODUCTION AND MARKETING vol 1 (2008) PARA 1246. As to the control of hazardous and dangerous substances generally see HEALTH AND SAFETY AT WORK vol 53 (2009) PARA 619 et seq; ENVIRONMENTAL QUALITY AND PUBLIC HEALTH vol 46 (2010) PARA 788 et seq.

2 The principal enactment relating to poisons is the Poisons Act 1972, which came into force on 1 February 1978, ie immediately after all the amendments of the Pharmacy and Poisons Act 1933 made by the Medicines Act 1968 Schs 5, 6, were brought into operation by order under s 136: Poisons Act 1972 s 13(1); Medicines Act 1968 (Commencement No 7) Order 1977, SI 1977/2128. As to the transitional provisions see the Poisons Act 1972 s 13(2)-(6). Dealings in certain narcotic and addictive drugs are controlled by the Misuse of Drugs Act 1971: see PARA 237 et seq ante. Dealings with medicinal products are controlled by the Medicines Act 1968: see PARA 1 et seq ante.

3 Ie the Poisons Rules 1982, SI 1982/218 (as amended): see PARA 289 post. Further provisions relating to poisons are contained in the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002, SI 2002/1689, and the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2004, SI 2004/568: see PARAS 298-299 post.

4 See PARA 293 et seq post. A visiting force or headquarters, members of such a force or headquarters, persons employed in the service of such a force, and property used for the purposes of such a force or headquarters are exempt from the operation of the Poisons Act 1972 to the extent that Crown immunity exempts home forces from it: see the Visiting Forces and International Headquarters (Application of Law) Order 1999, SI 1999/1736, art 12(1), Sch 5; and ARMED FORCES vol 2(2) (Reissue) PARA 142.

UPDATE

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NOTE 3--SI 2002/1689 replaced: Chemicals (Hazard Information and Packaging for Supply) Regulations 2009, SI 2009/716.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(1) THE CONTROL OF POISONS/285. The Poisons Board.

285. The Poisons Board.

The Poisons Board is an advisory committee composed of 16 members¹ representing the government departments specially interested in poisons and the professions of medicine and pharmacy². The Board's principal function is concerned with the preparation and modification from time to time of the Poisons List³ and any poisons rules⁴. The appointed members of the Board hold office for a term of three years⁵. If the place of an appointed member becomes vacant before his term expires, whether by death, resignation or otherwise, the vacancy must be filled by a person appointed by the body or person by whom the vacating member was appointed, and any person appointed to fill a casual vacancy holds office so long only as the member to whose place he was appointed would have held office⁶. Upon ceasing to be a member an appointed member is eligible for reappointment⁷. The Board's powers may be exercised notwithstanding any vacancy among its members⁸ and its quorum is 11⁹.

1 Poisons Act 1972 s 1(1), Sch 1 para 1. As to the members of the Board, and the persons responsible for their appointment, see Sch 1 para 3 (amended by virtue of the Transfer of Functions (Medicines and Poisons) Order 1999, SI 1999/3142, art 2(4); and by the Ministry of Agriculture, Fisheries and Food (Dissolution) Order 2002, SI 2002/794, art 5(1), Sch 1 para 18). The Secretary of State may from time to time, if he thinks fit, appoint up to three additional members of the Board: Poisons Act 1972 Sch 1 para 2. The chairman of the Board is such member as the Secretary of State may appoint: Sch 1 para 4. As to the Secretary of State see PARA 3 note 3 ante. So far as they are exercisable in relation to Wales, all functions of a Minister of the Crown under the Poisons Act 1972, except s 1(2) (see note 2 infra), are transferred to the National Assembly for Wales, save that the functions of the Secretary of State in appointing additional members to the Poisons Board under Sch 1 paras 2, 3 and the functions of the Secretary of State under Sch 1 para 4 are exercisable concurrently with the Secretary of State: see the National Assembly for Wales (Transfer of Functions) Order 1999, SI 1999/672, art 2, Sch 1. As to the National Assembly for Wales see CONSTITUTIONAL LAW AND HUMAN RIGHTS.

2 See the Poisons Act 1972 s 1(1), Sch 1. The procedure of the Poisons Board is (subject to any regulations made by the Board with the approval of the Secretary of State) such as the Board may determine: s 1(2). Regulations made by the Board are not statutory instruments and are not noted in this work.

3 See *ibid* s 2; and PARA 286 post.

4 See *ibid* s 7; and PARA 289 post.

5 *Ibid* Sch 1 para 5.

6 *Ibid* Sch 1 para 6.

7 *Ibid* Sch 1 para 7.

8 *Ibid* Sch 1 para 8.

9 *Ibid* Sch 1 para 9.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(1) THE CONTROL OF POISONS/286. The Poisons List.

286. The Poisons List.

There is a list of substances treated as poisons for the purposes of the Poisons Act 1972, which is called 'the Poisons List'¹. The Secretary of State² may from time to time, after consultation with or on the recommendation of the Poisons Board³, by order⁴ amend or vary the Poisons List as he thinks proper⁵. If the Secretary of State by order makes amendments or variations in the Poisons List in which the Board does not concur⁶, he must, together with the statutory instrument containing the order, lay before each House of Parliament a statement of his reasons for making the order⁷.

The Poisons List is divided into two parts⁸. In determining the distribution of poisons between Part I and Part II of the Poisons List regard is to be had to the desirability of restricting Part II to articles which are in common use, or likely to come into common use, for purposes other than the treatment of human ailments, and which it is reasonably necessary to include in Part II if the public is to have adequate facilities for obtaining them⁹.

1 Poisons Act 1972 s 2(1), (2). The present Poisons List is contained in the Schedule to the Poisons List Order 1982, SI 1982/217 (amended by SI 1986/9; SI 1992/2292).

2 As to the Secretary of State see PARA 3 note 3 ante. See also PARA 285 note 1 ante.

3 As to the Poisons Board see PARA 285 ante.

4 The power to make such orders is exercisable by statutory instrument, which is subject to annulment in pursuance of a resolution of either House of Parliament: Poisons Act 1972 s 10(1). As to the annulment of statutory instruments see STATUTES vol 44(1) (Reissue) PARA 1516.

5 Ibid s 2(2).

6 Ibid s 10(2)(a).

7 Ibid s 10(2). As to the laying of documents before Parliament see PARLIAMENT vol 34 (Reissue) PARA 941.

8 Ibid s 2(3). As to Part I poisons see PARA 287 post; and as to Part II poisons see PARA 288 post.

9 Ibid s 2(4).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(1) THE CONTROL OF POISONS/287. Part I poisons.

287. Part I poisons.

Part I of the Poisons List¹ consists of those substances which, where they are non-medicinal poisons², are by virtue of, and subject to the provisions of, the Poisons Act 1972 to be prohibited from being sold except by a person lawfully conducting a retail pharmacy business³. The substances are:

- 262 (1) aluminium phosphide;
- 263 (2) arsenic; its compounds, other than those specified in Part II of the Poisons List⁴;
- 264 (3) barium, salts of, other than barium sulphate and the salts of barium specified in Part II of the Poisons List;
- 265 (4) bromomethane;
- 266 (5) chloropicrin;
- 267 (6) fluoroacetic acid; its salts; fluoroacetamide;
- 268 (7) hydrogen cyanide; metal cyanides, other than ferrocyanides and ferricyanides;
- 269 (8) lead acetates; compounds of lead with acids from fixed oils;
- 270 (9) magnesium phosphide;
- 271 (10) mercury, the following compounds of: nitrates of mercury; oxides of mercury; mercuric cyanide oxides; mercuric thiocyanate; ammonium mercuric chlorides; potassium mercuric iodides; organic compounds of mercury which contain a methyl (CH₃) group directly linked to the mercury atom;
- 272 (11) oxalic acid;
- 273 (12) phenols (phenol; phenolic isomers of the following: cresols, xylenols, monoethylphenols) except in substances containing less than 60 per cent, weight in weight, of phenols; compounds of phenols with a metal, except in substances containing less than the equivalent of 60 per cent, weight in weight, of phenols;
- 274 (13) phosphorus, yellow;
- 275 (14) strychnine; its salts; its quaternary compounds;
- 276 (15) thallium, salts of⁵.

1 As to the Poisons List see PARA 286 ante.

2 'Non-medicinal poison' means a substance which is included in Part I or Part II of the Poisons List and is neither: (1) a medicinal product as defined by the Medicines Act 1968 s 130 (see PARA 7 ante); nor (2) a substance in relation to which, by virtue of an order under the Medicines Act 1968 s 104 (as amended) or s 105 (as amended) (see PARA 9 ante), for the time being in force (and whether referred to in an order under s 104 (as amended) as a substance or as an article), the provisions of ss 51-54 (see PARA 133 et seq ante) and ss 69-77 (as amended) (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 902 et seq) have effect (whether or not subject to exceptions and modifications) as they have effect in relation to medicinal products so defined: Poisons Act 1972 s 11(1).

3 Ibid s 2(3). 'Person lawfully conducting a retail pharmacy business' must be construed in accordance with the Medicines Act 1968 s 69 (as amended) (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 909): Poisons Act 1972 s 11(2). For the meaning of 'retail pharmacy business' see PARA 51 note 3 ante; definition applied by s 11(2). As to the distribution of poisons between Part I and Part II of the Poisons List see s 2(4); and PARA 286 ante.

4 For Part II poisons see PARA 288 post.

5 Poisons List Order 1982, SI 1982/217, art 2(a), Schedule Pt I (amended by SI 1986/9; SI 1992/2292).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(1) THE CONTROL OF POISONS/288. Part II poisons.

288. Part II poisons.

Part II of the Poisons List¹ consists of those substances which, where they are non-medicinal poisons², are by virtue of, and subject to the provisions of, the Poisons Act 1972 to be prohibited from being sold except by a person lawfully conducting a retail pharmacy business³ or by a person⁴ whose name is entered in a local authority's list⁵. The substances are:

- 277 (1) aldicarb;
- 278 (2) alpha-chloralose;
- 279 (3) ammonia;
- 280 (4) arsenic, the following compounds of: calcium arsenites; copper acetoarsenite; copper arsenates; copper arsenites; lead arsenates;
- 281 (5) barium, the following salts of: barium carbonate; barium silicofluoride;
- 282 (6) carbofuran;
- 283 (7) cycloheximide;
- 284 (8) dinitrocresols (DNOC); their compounds with a metal or a base;
- 285 (9) dinoseb; its compounds with a metal or a base;
- 286 (10) dinoterb;
- 287 (11) drazoxolon; its salts;
- 288 (12) endosulfan;
- 289 (13) endothal; its salts;
- 290 (14) endrin;
- 291 (15) fentin, compounds of;
- 292 (16) formaldehyde;
- 293 (17) formic acid;
- 294 (18) hydrochloric acid;
- 295 (19) hydrofluoric acid; alkali metal bifluorides; ammonium bifluoride; alkali metal fluorides; ammonium fluoride; sodium silicofluoride;
- 296 (20) mercuric chloride; mercuric iodide; organic compounds of mercury except compounds which contain a methyl (CH₃) group directly linked to the mercury atom;
- 297 (21) metallic oxalates;
- 298 (22) methomyl;
- 299 (23) nicotine; its salts; its quaternary compounds;
- 300 (24) nitric acid;
- 301 (25) nitrobenzene;
- 302 (26) oxamyl;
- 303 (27) paraquat, salts of;
- 304 (28) phenols (as defined in Part I of the Poisons List⁶) in substances containing less than 60 per cent, weight in weight, of phenols; compounds of phenols with a metal in substances containing less than the equivalent of 60 per cent, weight in weight, of phenols;
- 305 (29) phosphoric acid;
- 306 (30) phosphorus, the following compounds: azinphos methyl, chlorfenvinphos, demephion, demeton-S-methyl, demeton-S-methyl sulphone, dialifos, dichlorvos, dioxathion, disulfoton, fonofos, mecarbam, mephosfolan, methidathion, mevinphos, omethoate, oxydemeton-methyl, PARATHION, phenkapton, phorate, phosphamidon, pirimiphos-ethyl, quinalphos, thiometon, thionazin, triazophos, vamidothion;
- 307 (31) potassium hydroxide;

308 (32) sodium hydroxide;
309 (33) sodium nitrite;
310 (34) sulphuric acid;
311 (35) thiofanox;
312 (36) zinc phosphide⁷.

1 As to the Poisons List see PARA 286 ante.

2 For the meaning of 'non-medicinal poison' see PARA 287 note 2 ante.

3 For the meaning of 'person lawfully conducting a retail pharmacy business' see PARA 250 note 3 ante, and for the meaning of 'retail pharmacy business' see PARA 51 note 3 ante; definitions applied by the Poisons Act 1972 s 11(2).

4 For the meaning of 'person' see PARA 21 note 7 ante.

5 Poisons Act 1972 s 2(3). For the meaning of 'local authority's list' see PARA 290 note 4 post. As to the distribution of poisons between Part I and Part II of the Poisons List see s 2(4); and PARA 286 ante.

6 See PARA 287 ante.

7 Poisons List Order 1982, SI 1982/217, art 2(b), Schedule Pt II (amended by SI 1992/2292).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(1) THE CONTROL OF POISONS/289. Poisons Rules.

289. Poisons Rules.

After consultation with or on the recommendation of the Poisons Board¹, the Secretary of State² may make rules, known as 'Poisons Rules'³, with respect to any of the following matters or for any of the following purposes⁴:

- 313 (1) the sale, whether wholesale or retail, or the supply of non-medicinal poisons, by or to any persons or classes of persons⁵, and in particular⁶: (a) for regulating or restricting the sale or supply of non-medicinal poisons by persons whose names are entered in a local authority's list⁷ and for prohibiting the sale of any specified non-medicinal poison or class of non-medicinal poisons by any class of such persons⁸; and (b) for dispensing with or relaxing with respect to non-medicinal poisons any of certain provisions of the Poisons Act 1972⁹ relating to the sale of non-medicinal poisons¹⁰;
- 314 (2) the storage, transport and labelling of non-medicinal poisons¹¹;
- 315 (3) the containers in which non-medicinal poisons may be sold or supplied¹²;
- 316 (4) the addition to non-medicinal poisons of specified ingredients for the purpose of rendering them readily distinguishable as non-medicinal poisons¹³;
- 317 (5) the compounding of non-medicinal poisons, and the supply of non-medicinal poisons on and in accordance with a prescription duly given by a doctor, a dentist, a veterinary surgeon or a veterinary practitioner¹⁴;
- 318 (6) the period for which any books required to be kept for the purposes of the Poisons Act 1972 are to be preserved¹⁵;
- 319 (7) the period for which any certificate¹⁶ certifying a person to be a person to whom a Part I poison may properly be sold is to remain in force¹⁷;
- 320 (8) for prescribing anything which is required by that Act to be prescribed¹⁸ by rules¹⁹.

The Secretary of State may issue to the Poisons Board a direction that its power to make recommendations as to the making of rules with respect to certain of these matters²⁰ must not be exercised except after consultation with such body of persons as is specified in the direction, being a body which is, in his opinion, representative of persons engaged in the manufacture of poisons or preparations containing poisons, and the Board must comply with any such direction²¹.

1 As to the Poisons Board see PARA 285 ante.

2 As to the Secretary of State see PARA 3 note 3 ante. See also PARA 285 note 1 ante.

3 Poisons Act 1972 s 11(2). As to the rules that have been made see the Poisons Rules 1982, SI 1982/218 (as amended).

4 Poisons Act 1972 s 7(1). The power to make rules with respect to non-medicinal poisons includes power to make rules with respect to any class of such poisons or any particular such poison: s 7(2). For the meaning of 'non-medicinal poison' see PARA 287 note 2 ante.

The power to make rules is exercisable by statutory instrument which is subject to annulment in pursuance of a resolution of either House of Parliament: s 10(1). As to the annulment of statutory instruments see STATUTES vol 44(1) (Reissue) PARA 1516. If the Secretary of State makes rules in which the Poisons Board does not concur (s 10(2)(b)), he must lay before each House of Parliament a statement of his reasons for making the rules,

together with the statutory instrument containing the rules (s 10(2)). As to the laying of documents before Parliament see PARLIAMENT vol 34 (Reissue) PARA 941.

5 For the meaning of 'person' see PARA 21 note 7 ante.

6 Poisons Act 1972 s 7(1)(a).

7 For the meaning of 'local authority's list' see PARA 290 note 4 post.

8 Poisons Act 1972 s 7(1)(a)(i).

9 *le* *ibid* ss 1-6.

10 *Ibid* s 7(1)(a)(ii). As to such rules see PARA 294 *et seq* post.

11 *Ibid* s 7(1)(b). As to provisions relating to such matters see PARAS 298-299 post.

12 *Ibid* s 7(1)(c). As to provisions relating to such matters see PARA 298 post.

13 *Ibid* s 7(1)(d).

14 *Ibid* s 7(1)(e). 'Doctor' means a registered medical practitioner within the meaning of the Interpretation Act 1978 Sch 1 (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 4); Poisons Act 1972 s 11(2) (definition substituted by the Medical Act 1983 s 56(1), Sch 5). 'Dentist' means a person registered in the dentists register kept under the Dentists Act 1984 or a person entered in the list of visiting EEA practitioners under Sch 4 (as amended); Poisons Act 1972 s 11(2) (definition amended by the Dentists Act 1984 s 54(1), Sch 5 para 4; and the Dental Qualifications (Recognition) Regulations 1996, SI 1996/1496, reg 7(c)). As to the registration of dentists see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 417 *et seq*. 'Veterinary surgeon' means a person registered in the register of veterinary surgeons kept under the Veterinary Surgeons Act 1966 s 2 (see ANIMALS vol 2 (2008) PARA 1133); and 'veterinary practitioner' means a person registered in the supplementary veterinary register kept under the Veterinary Surgeons Act 1966 s 8 (see ANIMALS vol 2 (2008) PARA 1134); Poisons Act 1972 s 11(2).

15 *Ibid* s 7(1)(f).

16 *le* a certificate given under *ibid* s 3(2)(a)(i): see PARA 296 post.

17 *Ibid* s 7(1)(g).

18 'Prescribed' means prescribed by the Poisons Rules 1982, SI 1982/218 (as amended); Poisons Act 1972 s 11(2).

19 *Ibid* s 7(1)(h).

20 *le* those specified in *ibid* s 7(1)(a)(i), (b), (c), (d): see heads (1)(a), (2)-(4) in the text.

21 *Ibid* s 7(3). The Secretary of State may from time to time revoke or vary any such direction, without prejudice to the issue of a new one: s 7(4).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(2) SALE, STORAGE AND TRANSPORT OF POISONS/(i) Local Authorities' Lists/290. Listed sellers.

(2) SALE, STORAGE AND TRANSPORT OF POISONS

(i) Local Authorities' Lists

290. Listed sellers.

Every local authority¹ must keep a list of persons² who are entitled, on premises in respect of which their names are entered, to sell non-medicinal poisons³ which are substances included in Part II of the Poisons List⁴; and must enter in the list the name of any person who, having premises in the area of the local authority, makes an application in the prescribed form⁵ to have his name entered in the list in respect of those premises⁶.

Fees are payable to the local authority in respect of the entry of names in the list⁷, the making of alterations in the list in relation to the premises in respect of which a name is entered⁸, and the retention of names on the list in years⁹ subsequent to the year of entry in the list¹⁰.

1 'Local authority' means, in relation to England, the council of a county, metropolitan district or London borough or the Common Council of the City of London; and, in relation to Wales, the council of a county or county borough: Poisons Act 1972 s 11(2) (definition amended by the Statute Law (Repeals) Act 1978; the Local Government Act 1985 s 16, Sch 8 para 16; and the Local Government (Wales) Act 1994 s 66(6), (8), Sch 16 para 39, Sch 18). As to local government areas and authorities in England and Wales see LOCAL GOVERNMENT vol 69 (2009) PARA 22 et seq. As to the London boroughs and their councils see LONDON GOVERNMENT vol 29(2) (Reissue) PARAS 30, 35-39, 59 et seq. As to the Common Council of the City of London see LONDON GOVERNMENT vol 29(2) (Reissue) PARAS 51-55.

2 For the meaning of 'person' see PARA 21 note 7 ante.

3 For the meaning of 'non-medicinal poison' see PARA 287 note 2 ante.

4 Poisons Act 1972 s 5(1). As to the Poisons List see PARA 286 ante; and as to Part II poisons see PARA 288 ante. A list kept by a local authority under s 5 is called a 'local authority's list': s 11(2). As to refusal of entry in, and removal from, a list see PARA 291 post; and as to the use of titles in connection with entries in a list see PARA 292 post.

5 For the prescribed form see the Poisons Rules 1982, SI 1982/218, r 24(1), Sch 8.

6 Poisons Act 1972 s 5(2). A local authority's list must: (1) include particulars of the premises in respect of which the name of any person is entered in the list (s 6(1)(a)); (2) subject to head (1) supra, be in such form as may be prescribed (s 6(1)(b)); and (3) be open at all reasonable times to the inspection of any person without fee (s 6(1)(c)). For the prescribed form of the list see the Poisons Rules 1982, SI 1982/218, r 24(2), Sch 9.

7 Poisons Act 1972 s 6(2)(a). The fees payable are such reasonable fees as the authority may determine: s 6(2) (amended by the Local Government, Planning and Land Act 1980 s 1 (6), Sch 6 para 13 (2)).

8 Poisons Act 1972 s 6(2)(b). As to the level of fees see note 7 supra.

9 'Year' means a period of 12 months beginning on such date as the local authority may from time to time determine: *ibid* s 6(2)(c). For the meaning of 'month' see PARA 22 note 15 ante.

10 *Ibid* s 6(2)(c). As to the level of fees see note 7 supra.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(2) SALE, STORAGE AND TRANSPORT OF POISONS/(i) Local Authorities' Lists/291. Refusal of entry in, and removal from, list.

291. Refusal of entry in, and removal from, list.

A local authority¹ may refuse to enter in, or may remove from, the local authority's list² the name of any person³ who fails to pay the requisite fees⁴ or who in the authority's opinion is, for any sufficient reason relating either to him personally⁵ or to his premises, not fit to be on the list⁶. Any person aggrieved by the refusal of a local authority to enter his name in the list or by the removal of his name from it may appeal to the Crown Court⁷.

If any person whose name is entered in a local authority's list is convicted before any court of any offence which, in the court's opinion, renders him unfit to be on the list, the court may, as part of the sentence, order his name to be removed from the list and direct that he be disqualified for having it entered in any local authority's list for such period as may be specified in the order⁸.

1 For the meaning of 'local authority' see PARA 290 note 1 ante.

2 For the meaning of 'local authority's list' see PARA 290 note 4 ante.

3 For the meaning of 'person' see PARA 21 note 7 ante.

4 As to the fees see PARA 290 notes 7, 8, 10 ante.

5 'Relating to him personally' means, in relation to a body corporate, relating personally to the members of the board or to the managers or other officers of the body corporate: Poisons Act 1972 s 5(5). As to whether a reason relating personally to only one member of the board or one manager or other officer is sufficient, see the Interpretation Act 1978 s 6(c), which provides that, unless the contrary intention appears, words denoting the plural include the singular (and vice versa). 'The board', in relation to a body corporate, means the persons controlling that body, by whatever name called: Poisons Act 1972 s 11(2). As to bodies corporate see COMPANIES; CORPORATIONS.

6 Ibid s 5(3) (amended by the Local Government, Planning and Land Act 1980 s 1(6), Sch 6 para 13(1)).

7 Poisons Act 1972 s 5(4). As to the Crown Court see COURTS vol 10 (Reissue) PARA 621 et seq.

8 Ibid s 6(3).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(2) SALE, STORAGE AND TRANSPORT OF POISONS/(i) Local Authorities' Lists/292. Use of titles.

292. Use of titles.

It is not lawful for any person¹ whose name is entered in a local authority's list² to use in connection with his business any title, emblem or description reasonably calculated³ to suggest that he is entitled to sell any poison which he is not entitled to sell⁴. If any person acts in contravention of this provision, he is liable to a penalty⁵.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 For the meaning of 'local authority's list' see PARA 290 note 4 ante.

3 'Reasonably calculated' must mean reasonably calculated to persons who are qualified to exercise reason upon the subject, and that does not exclude, but rather includes and lays emphasis on, those who are instructed and educated persons in touch with and having some knowledge of the profession: *A-G v Weeks* [1932] 1 Ch 211 at 221, CA, per Lord Hanworth MR (a decision in connection with the use of titles and descriptions by registered dentists: see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 410).

4 Poisons Act 1972 s 6(4).

5 See *ibid* s 6(4) (amended by virtue of the Criminal Justice Act 1982 s 46). Such a person is liable on summary conviction, in respect of each offence, to a fine not exceeding level 2 on the standard scale and, in the case of a continuing offence, to a further fine not exceeding £5 for every day subsequent to the day on which he is convicted of the offence during which the contravention continues: Poisons Act 1972 s 6(4) (as so amended). As to the standard scale see PARA 6 note 22 ante.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(2) SALE, STORAGE AND TRANSPORT OF POISONS/(ii) Restrictions/293. Restrictions generally.

(ii) Restrictions

293. Restrictions generally.

Two classes of persons are entitled to sell non-medicinal poisons¹ by retail, namely persons lawfully conducting a retail pharmacy business², who may sell poisons included in both parts of the Poisons List³, and persons whose names are included in a local authority's list⁴, who may sell poisons in Part II of that list⁵.

It is not lawful for a non-medicinal poison to be exposed for sale in, or offered for sale by means of, an automatic machine⁶. Detailed requirements are imposed as respects the labelling of poisons and containers for them⁷, and as to their storage and transport⁸.

1 For the meaning of 'non-medicinal poison' see PARA 287 note 2 ante.

2 For the meaning of 'person lawfully conducting a retail pharmacy business' see PARA 250 note 3 ante; definition applied by the Poisons Act 1972 s 11(2).

3 See *ibid* s 3(1)(a), (b)(i); and PARA 294 post. As to the Poisons List see PARA 286 ante.

4 For the meaning of 'local authority's list' see PARA 290 note 4 ante.

5 See the Poisons Act 1972 s 3(1)(b)(ii); and PARA 295 post. As to Part II of the Poisons List see PARA 288 ante.

6 *Ibid* s 3(3).

7 See PARA 298 post.

8 See PARA 299 post.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(2) SALE, STORAGE AND TRANSPORT OF POISONS/(ii) Restrictions/294. Sales through retail pharmacy businesses.

294. Sales through retail pharmacy businesses.

Subject to exemptions¹, it is not lawful for a person²:

- 321 (1) to sell³ any non-medicinal poison⁴ included in Part I of the Poisons List⁵ unless he is a person lawfully conducting a retail pharmacy business⁶, the sale is effected on premises which are a registered pharmacy⁷, and the sale is effected by or under the supervision of a pharmacist⁸;
- 322 (2) to sell any non-medicinal poison included in Part II of the Poisons List⁹ unless he is a person lawfully conducting a retail pharmacy business and the sale is effected on premises which are a registered pharmacy¹⁰.

It is not lawful for any shopkeeper to sell poisons¹¹ on any premises used for or in connection with his retail business, notwithstanding that the sale is an exempted sale¹², unless he complies with these provisions¹³. Nor is it lawful for any person lawfully conducting a retail pharmacy business to sell any specified poison¹⁴, notwithstanding that it is a Part II poison, unless the sale is effected by or under the supervision of a pharmacist¹⁵.

1 For exemptions see PARAS 300-301 post.

2 For the meaning of 'person' see PARA 21 note 7 ante.

3 An agreement to sell does not of itself constitute a sale, which is incomplete without the passing of property: see eg *Mischew v Springett* [1942] 2 KB 331, [1942] 2 All ER 349; *Watson v Coupland* [1945] 1 All ER 217, DC. A sale is, however, effected where a person appropriates or transfers goods under an agreement for the sale of unascertained goods: *Preston v Albuery* [1964] 2 QB 796, [1963] 3 All ER 897, DC. See further SALE OF GOODS AND SUPPLY OF SERVICES vol 41 (2005 Reissue) PARA 1 et seq.

4 For the meaning of 'non-medicinal poison' see PARA 287 note 2 ante.

5 As to the Poisons List see PARA 286 ante; and as to Part I poisons see PARA 287 ante.

6 Poisons Act 1972 s 3(1)(a)(i). For the meaning of 'person lawfully conducting a retail pharmacy business' see PARA 250 note 3 ante; definition applied by s 11(2).

7 Ibid s 3(1)(a)(ii). For the meaning of 'registered pharmacy' see PARA 51 note 3 ante; definition applied by s 11(2).

8 Ibid s 3(1)(a)(iii). 'Pharmacist' means a person registered in the register of pharmaceutical chemists established in pursuance of the Pharmacy Act 1852 and maintained in pursuance of the Pharmacy Act 1954 s 2(1) (see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 888); Poisons Act 1972 s 11(2). It is not sufficient for the registered pharmacist to be in another room on the premises, out of sight and hearing: *Roberts v Littlewood's Mail Order Stores Ltd* [1943] 1 KB 269, [1943] 1 All ER 271, DC. However, the requirement is satisfied where a customer in a self-service store himself takes a poison from the shelf and pays for it at a cash desk supervised by a pharmacist: *Pharmaceutical Society of Great Britain v Boots Cash Chemists (Southern) Ltd* [1953] 1 QB 401, [1953] 1 All ER 482, CA.

9 As to Part II poisons see PARA 288 ante.

10 Poisons Act 1972 s 3(1)(b)(i). Part II poisons may also be sold by persons on a local authority's list: see s 3(1)(b)(ii); and PARA 295 post.

11 'Poison' means a non-medicinal poison: Poisons Rules 1982, SI 1982/218, r 2(1). The Poisons Rules 1982, SI 1982/218 (as amended) do not have effect in relation to any poison other than a non-medicinal poison: r 2(3).

12 'Exempted sale' means a sale within any of the provisions of the Poisons Act 1972 s 4(a)-(e) (see PARA 300 post): Poisons Rules 1982, SI 1982/218, r 2(1).

13 Ibid r 3. The provisions referred to in the text are those of the Poisons Act 1972 s 3(1)(a) or (b): see the text to notes 1-10 supra.

14 In any poison included in ibid Sch 1 (amended by SI 1985/1077; SI 1986/10). For certain special exemptions see PARA 301 post. The poisons included in the Poisons Rules 1982, SI 1982/218, Sch 1 (as amended) are:

- 95 (1) aldicarb;
- 96 (2) alpha-chloralose;
- 97 (3) aluminium phosphide;
- 98 (4) arsenic; its compounds, except substances containing less than the equivalent of 0.0075% of arsenic (As);
- 99 (5) barium, salts of, other than barium sulphate;
- 100 (6) bromomethane;
- 101 (7) carbofuran;
- 102 (8) chloropicrin;
- 103 (9) cycloheximide;
- 104 (10) dinitrocresols (DNOC); their compounds with a metal or a base; except winter washes containing not more than the equivalent of 5% of dinitrocresols;
- 105 (11) dinoseb; its compounds with a metal or a base;
- 106 (12) dinoterb;
- 107 (13) drazoxolon; its salts;
- 108 (14) endosulfan;
- 109 (15) endothal; its salts;
- 110 (16) endrin;
- 111 (17) fentin, compounds of;
- 112 (18) fluoroacetic acid; its salts; fluoroacetamide;
- 113 (19) hydrogen cyanide except substances containing less than 0.15%, weight in weight, of hydrogen cyanide (HCN); metal cyanides, other than ferrocyanides and ferricyanides, except substances containing less than the equivalent of 0.1%, weight in weight, of hydrogen cyanide (HCN);
- 114 (20) lead, compounds of, with acids from fixed oils;
- 115 (21) magnesium phosphide;
- 116 (22) mercuric chloride except substances containing less than 1% of mercuric chloride;
- 117 (23) mercuric iodide except substances containing less than 2% of mercuric iodide; nitrates of mercury except substances containing less than the equivalent of 3%, weight in weight, of mercury (Hg); potassio-mercuric iodides except substances containing less than the equivalent of 1% of mercuric iodide; organic compounds of mercury except substances, not being aerosols, containing less than the equivalent of 0.2%, weight in weight, of mercury (Hg);
- 118 (24) methomyl;

- 119 (25) nicotine; its salts; its quaternary compounds;
- 120 (26) oxamyl;
- 121 (27) paraquat, salts of;
- 122 (28) phosphorus, the following compounds: azinphosmethyl; chlorfen vinphos; demephion; demeton-S-methyl; demeton-S-methyl sulphone; dialifos; dichlorvos; dioxathion; disulfoton; fonofos; mecarbam; mephosfolan; methidathion; mevinphos; omethoate; oxydemetonmethyl; parathion; phenkapton; phorate; phosphamidon; pirimiphos-ethyl; quinalphos; thiometon; thionazin; triazophos; vamidothion;
- 123 (29) strychnine; its salts; its quaternary compounds; except substances containing less than 0.2% of strychnine;
- 124 (30) thallium, salts of;
- 125 (31) thiofanox;
- 126 (32) zinc phosphide.

15 Ibid r 9.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(2) SALE, STORAGE AND TRANSPORT OF POISONS/(ii) Restrictions/295. Sales by listed sellers.

295. Sales by listed sellers.

Subject to certain exemptions¹, it is not lawful for a person² (other than a person lawfully conducting a retail pharmacy business³) to sell⁴ any non-medicinal poison⁵ included in Part II of the Poisons List⁶ unless his name is entered in a local authority's list⁷ in respect of the premises on which the poison is sold⁸. It is not lawful for a shopkeeper to sell poisons⁹ on any premises used for or in connection with his retail business, notwithstanding that the sale is an exempted sale¹⁰, unless this provision is complied with¹¹.

No shopkeeper is entitled, by virtue of being a listed seller of Part II poisons¹², to sell any poison which has, since being obtained by him, been subject to any form of manipulation, treatment or processing as a result of which the poison has been exposed¹³, or to sell any specified poisons¹⁴ unless the sale is effected by himself or by a responsible deputy¹⁵. No person is entitled by virtue of being a listed seller of Part II poisons to sell any of certain poisons¹⁶ unless the purchaser is engaged in the trade or business of agriculture, horticulture or forestry and requires the poison for the purpose of that trade or business¹⁷; nor to sell certain other poisons¹⁸ except specified articles or substances¹⁹.

1 For exemptions see PARAS 300-301 post.

2 For the meaning of 'person' see PARA 21 note 7 ante.

3 As to sales of Part II poisons by such persons see PARA 294 ante. For the meaning of 'person lawfully conducting a retail pharmacy business' see PARA 250 note 3 ante; definition applied by the Poisons Act 1972 s 11(2).

4 As to what amounts to a sale see PARA 294 note 3 ante.

5 For the meaning of 'non-medicinal poison' see PARA 287 note 2 ante.

6 As to the Poisons List see PARA 286 ante; and as to Part II poisons see PARA 288 ante.

7 For the meaning of 'local authority's list' see PARA 290 note 4 ante.

8 Poisons Act 1972 s 3(1)(b)(ii).

9 For the meaning of 'poison' see PARA 294 note 11 ante.

10 For the meaning of 'exempted sale' see PARA 294 note 12 ante.

11 Poisons Rules 1982, SI 1982/218, r 3.

12 'Listed seller of Part II poisons' means a person whose name is for the time being entered in a local authority's list: *ibid* r 2(1).

13 *Ibid* r 10(1)(a) (substituted by SI 1985/1077). For general exemptions see PARA 300 post.

14 Ie any poison included in the Poisons Rules 1982, SI 1982/218, Sch 1 (as amended): see PARA 294 note 14 ante.

15 *Ibid* r 10(1)(b). 'Responsible deputy' means a person nominated as a deputy on the seller's form of application under r 24, Sch 8, for entry as a listed seller, or any person substituted, by written notice to the local authority, for a person so nominated and more than two deputies may be nominated at the same time in respect of one set of premises: r 10(1).

16 As to such poisons see *ibid* Sch 5 Pt B.

17 *Ibid* r 10(2)(b).

18 As to such poisons see *ibid* Sch 5 Pt A col 1.

19 *Ibid* r 10(2)(a) (amended by SI 1985/1077). As to the specified articles and substances (which include eg preparations for use in agriculture, horticulture or forestry; agricultural, horticultural and forestal insecticides or fungicides; preparations for the destruction of rats or mice; and photographic solutions or materials) see the Poisons Rules 1982, SI 1982/218, Sch 5 Pt A col 2.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(2) SALE, STORAGE AND TRANSPORT OF POISONS/(ii) Restrictions/296. Persons to whom certain poisons may be sold.

296. Persons to whom certain poisons may be sold.

Subject to certain exemptions¹, it is not lawful to sell², or supply in the form of commercial sample otherwise than on sale³, any non-medicinal poison⁴ which is a substance included in Part I of the Poisons List⁵ to any person⁶ unless that person is either: (1) certified, in writing⁷ in the prescribed manner⁸ by an authorised person⁹, to be a person to whom the poison may properly be sold or supplied¹⁰; or (2) is known, by the seller or supplier or by a registered pharmacist¹¹ in the employment of the seller or supplier at the premises where the sale or supply is effected, to be such a person¹². The seller or supplier of any such poison must not deliver it until he has made or caused to be made an entry in a book kept for the purpose¹³, stating in the prescribed form¹⁴ particulars of the transaction¹⁵, and the purchaser has signed the entry¹⁶.

These provisions as to the persons to whom poisons may be sold¹⁷ and as to the recording of sales¹⁸ apply to exempted sales¹⁹ other than sales of poisons to be exported to purchasers outside the United Kingdom²⁰; they do not, however, apply to the sale or supply of any article by its manufacturer or by a person carrying on a business in the course of which poisons are regularly sold by way of wholesale dealing²¹, if the article is sold or supplied to a person carrying on a business in the course of which poisons are regularly sold or are regularly used in the manufacture of other articles²², and the seller or supplier is reasonably satisfied that the purchaser requires the article for the purpose of that business²³.

1 For exemptions see PARAS 300-301 post.

2 As to what amounts to a sale see PARA 294 note 3 ante.

3 See the Poisons Rules 1982, SI 1982/218, r 6(1).

4 For the meaning of 'non-medicinal poison' see PARA 287 note 2 ante.

5 As to the Poisons List see PARA 286 ante; and as to Part I poisons see PARA 287 ante. The provisions of the Poisons Act 1972 s 3(2) apply with respect to all poisons included in the Poisons Rules 1982, SI 1982/218, Sch 1 (as amended) (see PARA 294 note 14 ante), whether or not the poison sold is a poison included in Part I of the Poisons List, and do not apply with respect to any other poison: r 5. For the meaning of 'poison' see PARA 294 note 11 ante. Certain substances are, however, exempted: see r 5 proviso (ii).

6 Poisons Act 1972 s 3(2)(a). For the meaning of 'person' see PARA 21 note 7 ante.

7 For the meaning of 'writing' see PARA 265 note 2 ante.

8 For the form of the certificate and the particulars which it must contain see the Poisons Rules 1982, SI 1982/218, r 25(1), Sch 10. On the sale, the seller must retain the certificate: r 25(3).

9 All householders are authorised to give certificates, provided that a certificate given by a householder who is not known to the seller or supplier as a responsible person of good character must be endorsed in the manner specified in ibid Sch 10 by a police officer in charge of a police station: r 25(2).

10 Poisons Act 1972 s 3(2)(a)(i).

11 For the meaning of 'pharmacist' see PARA 294 note 8 ante.

12 Poisons Act 1972 s 3(2)(a)(ii). In its application to sales by listed sellers of Part II poisons, this provision is deemed to be satisfied if the person to whom the poison is sold or supplied is known by the person in charge of the premises, or of the department of the business, in which the poison is sold or supplied, to be a person to

whom it may properly be sold or supplied: Poisons Rules 1982, SI 1982/218, r 5 proviso (i). For the meaning of 'listed sellers of Part II poisons' see PARA 295 note 12 ante. In its application to sales exempted by the Poisons Act 1972 s 4 (see PARA 300 post), and to the supply of commercial samples of poisons included in the Poisons Rules 1982, SI 1982/218, Sch 1 (as amended), it is deemed to be satisfied if the person to whom the poison or sample is sold or supplied is known by the person in charge of the department of the business through which the sale or supply is effected, to be a person to whom it may properly be sold or supplied: r 6(2).

13 Any book kept for the purposes of the Poisons Act 1972 must be preserved for two years after the last entry was made in it: see the Poisons Rules 1982, SI 1982/218, r 27.

14 For the prescribed form see *ibid* r 26, Sch 11.

15 Poisons Act 1972 s 3(2)(b)(i). These particulars are the date of sale or supply, the name and address of the person to whom it is sold or supplied and of the person who gave the certificate, if any, under s 3(2)(a)(i) (see the text to note 10 supra), the name and quantity of the article sold or supplied and the purposes for which it was stated by the purchaser to be required: s 3(2)(b)(i).

16 *Ibid* s 3(2)(b)(ii). The entry need not be so signed where the poison is required for the purposes of the purchaser's trade, business or profession and the following requirements are satisfied: (1) the seller must, before completing the sale, obtain a written order signed by the purchaser stating his name and address, trade, business or profession, the purpose for which the poison is required and the quantity (Poisons Rules 1982, SI 1982/218, r 6(3)(a)); (2) the seller must be reasonably satisfied that the signature is that of the person purporting to sign and that he does carry on the trade, business or profession stated, being one in which that poison is used (r 6(3)(b)); and (3) the seller must insert in the entry in the prescribed book 'signed order' with an identifiable reference number (r 6(3)(c)).

If the seller is reasonably satisfied that by reason of some emergency no signed order can be given or signed entry made and the poison is urgently required for the purpose of a person's trade, business or profession, the seller may deliver the poison on that person's undertaking to furnish such an order within 72 hours: r 6(3) proviso (amended by SI 1989/112). Any person who breaks such an undertaking, or who knowingly makes a false statement in order to obtain delivery under the Poisons Rules 1982, SI 1982/218, r 6(3) proviso (as amended), commits an offence: Poisons Act 1972 s 8(1) (amended by virtue of the Criminal Justice Act 1982 s 46); Poisons Rules 1982, SI 1982/218, r 6(3). As to offences and penalties see PARA 309 post.

17 *Ie* the provisions of the Poisons Act 1972 s 3(2)(a) and the Poisons Rules 1982, SI 1982/218, r 5.

18 *Ie* the provisions of the Poisons Act 1972 s 3(2)(b).

19 For the meaning of 'exempted sale' see PARA 294 note 12 ante.

20 Poisons Rules 1982, SI 1982/218, r 6(1). For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

21 'Sale by way of wholesale dealing' means sale to a person who buys for the purpose of selling again: Poisons Act 1972 s 11(2). That the person who buys cannot lawfully sell again is immaterial: see *Oxford v Sangers Ltd* [1965] 1 QB 491, [1965] 1 All ER 96, DC. However, it is not lawful to sell by way of wholesale dealing any Part I poison to a person carrying on the business of shopkeeping unless the seller: (1) has reasonable grounds for believing that the purchaser is a person lawfully conducting a retail pharmacy business (Poisons Rules 1982, SI 1982/218, r 11(a)); or (2) has received a statement signed by the purchaser or a person authorised by him or on his behalf to the effect that the purchaser does not intend to sell the poison on any premises used for or in connection with his retail business (r 11(b)). For the meaning of 'person lawfully conducting a retail pharmacy business' see PARA 250 note 3 ante; definition applied by the Poisons Act 1972 s 11(2).

22 Poisons Rules 1982, SI 1982/218, r 6(1) proviso (a).

23 *Ibid* r 6(1) proviso (b).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(2) SALE, STORAGE AND TRANSPORT OF POISONS/(ii) Restrictions/297. Sale of strychnine, cyanides and certain other poisons.

297. Sale of strychnine, cyanides and certain other poisons.

It is not lawful to sell¹ or supply strychnine, its salts or quaternary compounds², fluoroacetic acid, any salt of it or fluoroacetamide³, salts of thallium⁴, zinc phosphide⁵, sodium arsenites or potassium arsenites⁶ unless the substance is to be exported to purchasers outside the United Kingdom⁷, or to a person or institution concerned with scientific education or research or chemical analysis for the purposes of that education, research or analysis⁸, or it is to be sold by way of wholesale dealing⁹.

However, strychnine, its salts or quaternary compounds may be sold or supplied to a person producing a written authority in the prescribed form¹⁰, as may fluoroacetic acid, any salt of it or fluoroacetamide¹¹ or thallium sulphate¹². Salts of thallium may be sold to a local authority¹³ or a port health authority¹⁴ for the purpose of the exercise of its statutory powers¹⁵, or to a government department or an officer of the Crown for the purposes of the public service¹⁶; or, in the case of salts of thallium other than thallium sulphate, to a person, or body of persons, carrying on a business in the course of which salts of thallium are regularly used in the manufacture of other articles, for the purposes of that business¹⁷, or as an ingredient in any article not being an article intended for internal consumption by any person or animal¹⁸. Zinc phosphide may be sold to a local authority for the purpose of the exercise of its statutory powers¹⁹, or to a government department or an officer of the Crown for the purposes of the public service²⁰, or to a person, or body of persons, carrying on a trade or business for the purposes of that trade or business²¹.

Unless the sale is an exempted sale²², it is not lawful to sell calcium cyanide, potassium cyanide or sodium cyanide²³.

1 As to what amounts to a sale see PARA 294 note 3 ante.

2 Poisons Rules 1982, SI 1982/218, r 12(1).

3 Ibid r 12(2).

4 Ibid r 12(3).

5 Ibid r 12(4).

6 Ibid r 12(5).

7 Ibid r 12, Sch 12 Pt I para 1. For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

8 Ibid Sch 12 Pt I para 2.

9 Ibid Sch 12 Pt I para 3. For the meaning of 'sale by way of wholesale dealing' see PARA 296 note 21 ante.

10 See ibid r 12(1), Sch 12 Pt I paras 4, 5, Pts II, III. The authority must be retained by the seller: r 12(6).

11 See ibid r 12(2), Sch 12 Pt I para 6(1), Pt IV. The authority must be retained by the seller: r 12(6).

12 See ibid r 12(3), Sch 12 Pt I para 7(2), Pt V. The authority must be retained by the seller: r 12(6).

13 For these purposes, 'local authority' in Greater London means the Common Council of the City of London or the council of a London borough; and elsewhere in England or Wales means the council of a county or a district: ibid Sch 12 Pt I paras 6(2), 7(3). As to local government areas and authorities in England and Wales see LOCAL GOVERNMENT vol 69 (2009) PARA 22 et seq. As to the Common Council of the City of London see LONDON

GOVERNMENT vol 29(2) (Reissue) PARAS 51-55. As to the London boroughs and their councils see LONDON GOVERNMENT vol 29(2) (Reissue) PARAS 30, 35-39, 59 et seq.

14 'Port health authority' means the port health authority of the Port of London or a port health authority for the purposes of the Public Health Act 1936: Poisons Rules 1982, SI 1982/218, Sch 12 Pt I paras 6(2), 7(3). The relevant provisions of the Public Health Act 1936 are repealed and replaced by the Public Health (Control of Disease) Act 1984: see ENVIRONMENTAL QUALITY AND PUBLIC HEALTH vol 46 (2010) PARA 884 et seq. As to port health authorities see ENVIRONMENTAL QUALITY AND PUBLIC HEALTH vol 45 (2010) PARAS 102, 103.

15 See the Poisons Rules 1982, SI 1982/218, r 12(3), Sch 12 Pt I para 7(1)(a).

16 See *ibid* r 12(3), Sch 12 Pt I para 7(1)(b).

17 See *ibid* r 12(3), Sch 12 Pt I para 7(1)(c).

18 See *ibid* r 12(3), Sch 12 Pt I para 7(1)(d).

19 See *ibid* r 12(4), Sch 12 Pt I para 8(1)(a).

20 See *ibid* r 12(4), Sch 12 Pt I para 8(1)(b).

21 See *ibid* r 12(4), Sch 12 Pt I para 8(1)(c).

22 For the meaning of 'exempted sale' see PARA 294 note 12 ante.

23 Poisons Rules 1982, SI 1982/218, r 13.

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(iii) Labelling, Packaging, Storage and Transport

298. Labelling and packaging of poisons.

The provisions of the Poisons Act 1972¹ relating to the labelling of containers of non-medicinal poisons do not apply to the sale² of any such poison³. The regulation of the labelling and packaging of poisons is now governed by provisions relating to dangerous substances generally⁴.

It is not lawful to sell or supply any compressed hydrogen cyanide unless the container is labelled with the prescribed words⁵, except where the sale or supply is for export to purchasers outside the United Kingdom⁶.

1 The provisions which make it unlawful for a person to sell any non-medicinal poison, whether it is a substance included in Part I or in Part II of the Poisons List, unless the container of the poison is labelled in the prescribed manner: see the Poisons Act 1972 s 3(1)(c). For the meaning of 'non-medicinal poison' see PARA 287 note 2 ante. As to the Poisons List see PARA 286 ante; as to Part I poisons see PARA 287 ante, and as to Part II poisons see PARA 288 ante.

2 As to what amounts to a sale see PARA 294 note 3 ante.

3 Poisons Rules 1982, SI 1982/218, r 4 (substituted by SI 1985/1077).

4 See the Chemicals (Hazard Information and Packaging for Supply) Regulations 2002, SI 2002/1689; and HEALTH AND SAFETY AT WORK vol 53 (2009) PARAS 571-572.

5 Poisons Rules 1982, SI 1982/218, r 18(1) (renumbered by SI 1985/1077). The prescribed words are: 'Warning. This container holds poisonous gas and should only be opened and used by persons having expert knowledge of the precautions to be taken in its use': Poisons Rules 1982, SI 1982/218, r 18(1) (as so renumbered).

6 Ibid r 18(2) (substituted by SI 1985/1077). For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

UPDATE

298 Labelling and packaging of poisons

NOTE 4--SI 2002/1689 replaced: Chemicals (Hazard Information and Packaging for Supply) Regulations 2009, SI 2009/716.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(2) SALE, STORAGE AND TRANSPORT OF POISONS/(iii) Labelling, Packaging, Storage and Transport/299. Storage and transport of poisons.

299. Storage and transport of poisons.

It is not lawful to store any of certain poisons¹ in any retail shop or premises used in connection with it unless it is stored in a cupboard or drawer reserved solely for the storage of poisons², or in a part of the premises partitioned off or otherwise separated from the remainder and to which customers are not permitted access³, or on a shelf, directly under which no food⁴ is kept, reserved solely for the storage of poisons⁵. Additional notification and marking requirements are imposed on persons in control of sites at which a significant quantity of a dangerous substance is present⁶.

The transport of poisons is regulated by provisions relating to dangerous substances generally⁷.

1 For the meaning of 'poison' see PARA 294 note 11 ante. The poisons referred to in the text are those listed in the Poisons Rules 1982, SI 1982/218, Sch 1 (as amended): see PARA 294 note 14 ante.

2 Ibid r 21(a).

3 Ibid r 21(b).

4 'Food' includes a beverage: ibid r 2(1).

5 Ibid r 21(c). In the case of any such poison to be used in agriculture, horticulture or forestry, it is not lawful to store it on any shelf, or in any such part of the premises as is referred to in the text if food is kept in that part, or in any cupboard or drawer unless the cupboard or drawer is reserved solely for the storage of poisons to be used for those purposes: r 21 proviso.

6 See the Dangerous Substances (Notification and Marking of Sites) Regulations 1990, SI 1990/304 (as amended); and HEALTH AND SAFETY AT WORK vol 53 (2009) PARA 629.

7 See the Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2004, SI 2004/568 (as amended); and CARRIAGE AND CARRIERS vol 7 (2008) PARA 106.

UPDATE

299 Storage and transport of poisons

NOTE 7--SI 2004/568 replaced: see now Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009, SI 2009/1348.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(2) SALE, STORAGE AND TRANSPORT OF POISONS/(iv) Exemptions/300. Exemption of certain sales.

(iv) Exemptions

300. Exemption of certain sales.

Except as provided by the Poisons Rules 1982¹, nothing in the statutory provisions imposing restrictions on the sale of non-medicinal poisons² extends to or interferes with: (1) the sale of poisons by way of wholesale dealing³; (2) the sale of poisons to be exported to purchasers outside the United Kingdom⁴; (3) the sale of an article to a doctor, dentist, veterinary surgeon or veterinary practitioner for the purpose of his profession⁵; (4) the sale of an article for use in or in connection with any hospital, infirmary, dispensary or similar institution approved by an order, whether general or special, of the Secretary of State⁶; or (5) the sale of an article by a person⁷ carrying on a business in the course of which poisons are regularly sold either by way of wholesale dealing or for use by the purchasers in their trade or business: (a) to a person who requires the article for the purpose of his trade or business⁸; or (b) to a person who requires the article to enable him to comply with any requirements made by or in pursuance of any enactment⁹ with respect to the medical treatment of persons employed by him in any trade or business carried on by him¹⁰; or (c) to a government department or an officer of the Crown requiring the article for the purposes of the public service or any local authority¹¹ requiring the article in connection with the exercise by it of any statutory powers¹²; or (d) to a person or institution concerned with scientific education or research if the article is required for the purposes of that education or research¹³.

1 Ie the Poisons Rules 1982, SI 1982/218 (as amended). In particular, see r 3 (see PARAS 294-295 ante); rr 5, 6, 11 (see PARA 296 ante); and rr 12, 13 (see PARA 297 ante).

2 Ie nothing in the Poisons Act 1972 s 3(1), (2): see PARAS 294-296, 298 ante. For the meaning of 'non-medicinal poison' see PARA 287 note 2 ante.

3 Ibid s 4(a). For the meaning of 'sale by way of wholesale dealing' see PARA 296 note 21 ante.

4 Ibid s 4(b). For the meaning of 'United Kingdom' see PARA 7 note 3 ante.

5 Ibid s 4(c). For the meanings of 'doctor', 'dentist', 'veterinary surgeon' and 'veterinary practitioner' see PARA 289 note 14 ante.

6 Ibid s 4(d). As to the Secretary of State see PARA 3 note 3 ante. See also PARA 285 note 1 ante. The power to make orders is exercisable by statutory instrument, which is subject to annulment in pursuance of a resolution of either House of Parliament: s 10(1). As to the annulment of statutory instruments see STATUTES vol 44(1) (Reissue) PARA 1516. The Poisons (Approved Institutions) Order 1935, SR & O 1935/1240, continues to have effect: see the Poisons Act 1972 s 13(3). By this order there are approved for this purpose any hospital, infirmary or dispensary maintained by any public authority or maintained out of any public funds or by a charity or by voluntary subscriptions.

7 For the meaning of 'person' see PARA 21 note 7 ante.

8 Poisons Act 1972 s 4(e)(i).

9 'Enactment' does not include an enactment comprised in, or in an instrument made under, an Act of the Scottish Parliament: Interpretation Act 1978 s 5, Sch 1.

10 Poisons Act 1972 s 4(e)(ii).

11 le any local authority, whether as defined in the Poisons Act 1972 (see PARA 290 note 1 ante), or not: s 4(e)(iii).

12 Ibid s 4(e)(iii).

13 Ibid s 4(e)(iv).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(2) SALE, STORAGE AND TRANSPORT OF POISONS/(iv) Exemptions/301. Exemptions with respect to certain articles and substances.

301. Exemptions with respect to certain articles and substances.

Certain prescribed articles and substances¹ are specifically exempted from the restrictions imposed² on the sale and supply of poisons³; and other prescribed articles⁴ are exempted from the special restrictions imposed⁵ with respect to certain substances⁶.

1 I.e. adhesives, anti-fouling compositions, builders' materials, ceramics, cosmetic products, distempers, electrical valves, enamels, explosives, fillers, fireworks, fluorescent lamps, flux in any form used for soldering, glazes, glue, inks, lacquer solvents, loading materials, matches, medicated animal feeding stuffs, motor fuels and lubricants, paints, photographic paper, pigments, plastics, propellants, rubber, varnishes, vascular plants and their seeds: Poisons Rules 1982, SI 1982/218, r 8(a), Sch 4 Group I (amended by SI 1986/1704). 'Medicated animal feeding stuff' means an animal feeding stuff in which a medicinal product has been incorporated or in which a substance other than a medicinal product has been incorporated for a medicinal purpose: Poisons Rules 1982, SI 1982/218, r 2(1). For the meaning of 'animal' see PARA 3 note 7 ante; for the meaning of 'medicinal product' see PARA 7 ante; and for the meaning of 'a medicinal purpose' see PARA 8 ante (definitions applied by r 2(2)).

2 I.e. by the Poisons Act 1972 and by the Poisons Rules 1982, SI 1982/218 (as amended). In particular, see the Poisons Act 1972 s 3(1), (2) (see PARAS 294-296, 298 ante) and s 6 (see PARAS 290-292 ante).

3 Poisons Rules 1982, SI 1982/218, r 8(a). For the meaning of 'poison' see PARA 294 note 11 ante. Similar exemption is afforded, so far as any poison specified in Sch 4 Group II col 1, is concerned, with respect to any of the articles or substances specified opposite it in col 2 (amended by SI 1986/10; SI 1992/2293): see the Poisons Rules 1982, SI 1982/218, r 8(b). This exempts eg refrigerators containing ammonia; fire extinguishers containing barium chloride or bromomethane; seed treatments containing drazoxolon, mercuric chloride, mercuric iodide or organic compounds of mercury; batteries containing mercuric chloride; tree paints containing oxides of mercury; tobacco containing nicotine; photographic solutions containing formaldehyde; polishes and cleaners containing not more than 10% of oxalic acid dihydrate; creosotes, liquid disinfectants, antiseptics, soaps and tars containing phenols; toilet and cosmetic preparations containing traces of phenylmercuric salts; and aerosols containing small quantities of phosphorus compounds.

4 I.e. articles containing barium carbonate, zinc phosphide or alpha-chloralose where the article is one of the articles to which sale of the poison is restricted by the Poisons Rules 1982, SI 1982/218 (as amended): see rr 7, 10(2)(a), Sch 5 Pt A (r 7 amended by SI 1985/1077).

5 I.e. by the Poisons Rules 1982, SI 1982/218, rr 5, 6 (see PARA 296 ante), r 9 (see PARA 294 ante), and r 10(1) (see PARA 295 ante).

6 Ibid r 7. The substances referred to in the text are the poisons included in Sch 1 (as amended): see PARA 294 note 14 ante.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(3) ENFORCEMENT, PENALTIES AND PROCEEDINGS/(i) Enforcement/302. Enforcement duties of the Pharmaceutical Society.

(3) ENFORCEMENT, PENALTIES AND PROCEEDINGS

(i) Enforcement

302. Enforcement duties of the Pharmaceutical Society.

It is the duty of the Pharmaceutical Society of Great Britain¹ to take all reasonable steps by means of inspection and otherwise to enforce the provisions of the Pharmacy Act 1954² relating to the misuse of certificates of membership of the Society³, and to secure compliance by pharmacists⁴ and persons⁵ carrying on a retail pharmacy business⁶ with the provisions of the Poisons Act 1972⁷ and with the Poisons Rules 1982⁸.

1 As to the Pharmaceutical Society of Great Britain see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 881 et seq.

2 Ie the provisions of the Pharmacy Act 1954 s 20(2), (3): see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 898.

3 Poisons Act 1972 s 9(1)(a).

4 For the meaning of 'pharmacist' see PARA 294 note 8 ante.

5 For the meaning of 'person' see PARA 21 note 7 ante.

6 Poisons Act 1972 s 9(1)(b). For the meaning of 'retail pharmacy business' see PARA 51 note 3 ante; definition applied by s 11(2).

7 Ie the provisions of ibid ss 3-8.

8 Ie the Poisons Rules 1982, SI 1982/218 (as amended) (see PARA 289 ante). As to the appointment of inspectors for these purposes, and as to their powers, see PARAS 303-304 post.

UPDATE

302 Enforcement duties of the Pharmaceutical Society

TEXT AND NOTES 1-3--1972 Act s 9(1)(a) amended: SI 2007/289.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(3) ENFORCEMENT, PENALTIES AND PROCEEDINGS/(i) Enforcement/303. Appointment of Pharmaceutical Society inspectors.

303. Appointment of Pharmaceutical Society inspectors.

For the purpose of its enforcement duties¹, the Pharmaceutical Society of Great Britain² must appoint such number of inspectors as the Privy Council may direct³. A person is not qualified for such appointment unless he is a pharmacist⁴, and every such appointment is subject to the approval of the Privy Council⁵. An inspector so appointed holds office subject to such conditions with respect to salary and otherwise as the council of the Society, with the approval of the Privy Council, determines⁶.

1 See the Poisons Act 1972 s 9(1); and PARA 302 ante.

2 As to the Pharmaceutical Society of Great Britain see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 881 et seq.

3 Poisons Act 1972 s 9(1). As to the powers of such inspectors see PARA 304 post. As to the Privy Council see CONSTITUTIONAL LAW AND HUMAN RIGHTS vol 8(2) (Reissue) PARAS 521-526.

4 For the meaning of 'pharmacist' see PARA 294 note 8 ante.

5 Poisons Act 1972 s 9(2).

6 Ibid s 9(3).

UPDATE

303 Appointment of Pharmaceutical Society inspectors

TEXT AND NOTES--1972 Act s 9(1)-(3) amended: SI 2007/289.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(3) ENFORCEMENT, PENALTIES AND PROCEEDINGS/(i) Enforcement/304. Powers of Pharmaceutical Society inspectors.

304. Powers of Pharmaceutical Society inspectors.

An inspector appointed by the Pharmaceutical Society of Great Britain¹ has power:

- 323 (1) for the purpose of enforcing the provisions relating to the misuse of membership certificates² and for securing compliance by pharmacists³ and persons⁴ carrying on a retail pharmacy business⁵ with the provisions relating to poisons⁶, at all reasonable times⁷ to enter any registered pharmacy⁸; and
- 324 (2) for the purpose of securing compliance by other persons with those provisions, so far as they relate to substances included in Part I of the Poisons List⁹, to enter any premises in which he has reasonable cause to suspect¹⁰ that a breach of the law has been committed in relation to any such substances¹¹,

and in either case he has power to make such examination and inquiry and to do such other things, including the taking, on payment, of samples, as may be necessary for ascertaining whether those provisions are being complied with¹². However, this provision does not authorise an inspector to enter or inspect the premises, not being a shop, of a doctor, a dentist, a veterinary surgeon or a veterinary practitioner¹³.

¹ As to the appointment of such inspectors see PARA 303 ante; and as to the enforcement duties of the Society see PARA 302 ante. As to the Pharmaceutical Society of Great Britain see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 881 et seq.

² I.e. the provisions of the Pharmacy Act 1954 s 20(2), (3): see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 898.

³ For the meaning of 'pharmacist' see PARA 294 note 8 ante.

⁴ For the meaning of 'person' see PARA 21 note 7 ante.

⁵ For the meaning of 'retail pharmacy business' see PARA 51 note 3 ante; definition applied by the Poisons Act 1972 s 11(2).

⁶ I.e. the provisions of ibid ss 1-8 and of the Poisons Rules 1982, SI 1982/218 (as amended).

⁷ As to what is a reasonable time see *Small v Bickley* (1875) 32 LT 726, DC (Sunday afternoon might be reasonable).

⁸ Poisons Act 1972 s 9(4)(a). For the meaning of 'registered pharmacy' see PARA 51 note 3 ante; definition applied by s 11(2).

⁹ As to the Poisons List see PARA 286 ante; and as to Part I poisons see PARA 287 ante.

¹⁰ As to the meaning of 'reasonable cause to suspect' see *R v Banks* [1916] 2 KB 621, CCA; *R v Forde* [1923] 2 KB 400, CCA; *McArdle v Egan* (1933) 150 LT 412, CA; *R v Harrison* [1938] 3 All ER 134, CCA; *Nakkuda Ali v MF De S Jayaratne* [1951] AC 66, PC; *Registrar of Restrictive Trading Agreements v WH Smith & Son Ltd* [1969] 3 All ER 1065, [1969] 1 WLR 1460, CA; *R v IRC, ex p Rossminster Ltd* [1980] AC 952, sub nom *IRC v Rossminster Ltd* [1980] 1 All ER 80, HL.

¹¹ Poisons Act 1972 s 9(4)(b).

¹² Ibid s 9(4). It is an offence to obstruct an inspector in the exercise of his powers and to otherwise fail to co-operate with him: see s 9(8); and PARA 308 post.

13 Ibid s 9(9). For the meanings of 'doctor', 'dentist', 'veterinary surgeon' and 'veterinary practitioner' see PARA 289 note 14 ante.

UPDATE

304 Powers of Pharmaceutical Society inspectors

TEXT AND NOTES 1-12--1972 Act s 9(4) amended: SI 2007/289.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(3) ENFORCEMENT, PENALTIES AND PROCEEDINGS/(i) Enforcement/305. Enforcement duties of local authorities.

305. Enforcement duties of local authorities.

It is the duty of every local authority¹ by means of inspection and otherwise to take all reasonable steps to secure compliance by persons² who are not persons lawfully conducting a retail pharmacy business³ with the statutory provisions relating to poisons⁴ so far as those provisions relate to substances included in Part II of the Poisons List⁵, and to secure compliance with those provisions by persons lawfully conducting such a business at premises which are not a registered pharmacy⁶.

1 For the meaning of 'local authority' see PARA 290 note 1 ante.

2 For the meaning of 'person' see PARA 21 note 7 ante.

3 For the meaning of 'person lawfully conducting a retail pharmacy business' see PARA 250 note 3 ante; definition applied by the Poisons Act 1972 s 11(2).

4 Ie the provisions of ibid ss 1-8 and of the Poisons Rules 1982, SI 1982/218 (as amended).

5 Poisons Act 1972 s 9(5)(a). As to the Poisons List see PARA 286 ante; and as to Part II poisons see PARA 288 ante.

6 Ibid s 9(5)(b). For the meaning of 'registered pharmacy' see PARA 51 note 3 ante; definition applied by s 11(2). As to the appointment of inspectors for the purposes of this duty, and as to their powers, see PARAS 306-307 post.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(3) ENFORCEMENT, PENALTIES AND PROCEEDINGS/(i) Enforcement/306. Appointment of local authority inspectors.

306. Appointment of local authority inspectors.

For the purposes of its enforcement duties¹, a local authority² is under a duty to appoint inspectors³. An inspector appointed by the Pharmaceutical Society of Great Britain⁴ as one of its inspectors⁵ may, with the Society's consent, be appointed by a local authority to be also a local authority inspector⁶.

1 See the Poisons Act 1972 s 9(5); and PARA 305 ante.

2 For the meaning of 'local authority' see PARA 290 note 1 ante.

3 Poisons Act 1972 s 9(5). As to the powers of inspectors see PARA 307 post.

4 As to the Pharmaceutical Society of Great Britain see MEDICAL PROFESSIONS vol 30(1) (Reissue) PARA 881 et seq.

5 Ie under the Poisons Act 1972 s 9(1): see PARA 303 ante.

6 Ibid s 9(5).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(3) ENFORCEMENT, PENALTIES AND PROCEEDINGS/(i) Enforcement/307. Powers of local authority inspectors.

307. Powers of local authority inspectors.

An inspector appointed by a local authority¹ has power, for the purpose of the authority's enforcement duty², at all reasonable times³ to enter:

- 325 (1) any premises on which any person⁴ whose name is entered in a local authority's list⁵ carries on business; and
- 326 (2) any premises on which the inspector has reasonable cause to suspect⁶ that a breach of the law has been committed in respect of any substances included in Part II of the Poisons List⁷,

and in either case he has power to make such examination and inquiry and to do such other things, including the taking, on payment, of samples as may be necessary for the purposes of the inspection⁸. This provision does not, however, authorise an inspector to enter or inspect the premises, not being a shop, of a doctor, a dentist, a veterinary surgeon or a veterinary practitioner⁹.

An inspector appointed by a local authority has power with the consent of the local authority¹⁰ to institute proceedings under the Poisons Act 1972 before a magistrates' court¹¹ in the name of the authority and to conduct any proceedings so instituted by him notwithstanding that he is not of counsel or a solicitor¹².

1 For the meaning of 'local authority' see PARA 290 note 1 ante. As to the appointment of local authority inspectors see PARA 306 ante.

2 Ie the duty under the Poisons Act 1972 s 9(5): see PARA 305 ante.

3 As to what is a reasonable time see PARA 304 note 7 ante.

4 For the meaning of 'person' see PARA 21 note 7 ante.

5 For the meaning of 'local authority's list' see PARA 290 note 4 ante.

6 As to the meaning of 'reasonable cause to suspect' see PARA 304 note 10 ante.

7 As to the Poisons List see PARA 286 ante; and as to Part II poisons see PARA 288 ante.

8 Poisons Act 1972 s 9(6). It is an offence to obstruct an inspector in the exercise of his powers and to otherwise fail to co-operate with him: see s 9(8); and PARA 308 post.

9 Ibid s 9(9). For the meanings of 'doctor', 'dentist', 'veterinary surgeon' and 'veterinary practitioner' see PARA 289 note 14 ante.

10 As to the power of a local authority to authorise its officers to take proceedings see LOCAL GOVERNMENT vol 69 (2009) PARA 573.

11 As to magistrates' courts see MAGISTRATES vol 29(2) (Reissue) PARA 583 et seq.

12 Poisons Act 1972 s 9(7).

UPDATE

307 Powers of local authority inspectors

TEXT AND NOTE 12--Words 'notwithstanding that he is not of counsel or a solicitor' omitted: Poisons Act 1972 s 9(7) (amended by Legal Services Act 2007 Sch 21 para 27, Sch 23).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(3) ENFORCEMENT, PENALTIES AND PROCEEDINGS/(i) Enforcement/308. Obstruction etc of inspectors; information.

308. Obstruction etc of inspectors; information.

If a person:

- 327 (1) wilfully¹ delays or obstructs² an inspector, whether appointed by the Pharmaceutical Society of Great Britain³ or by a local authority⁴, in the exercise of his powers⁵; or
- 328 (2) refuses to allow any sample to be taken⁶; or
- 329 (3) fails without reasonable excuse to give any information which he is duly required to give⁷,

he is in respect of each offence liable to a penalty⁸.

1 'Wilfully' means deliberately and intentionally, not accidentally or inadvertently: *R v Senior* [1899] 1 QB 283 at 290, CCR, per Lord Russell CJ.

2 For the meaning of 'obstructs', in the context of obstructing a constable, see CRIMINAL LAW, EVIDENCE AND PROCEDURE vol 11(2) (2006 Reissue) PARA 735.

3 *Ie* under the Poisons Act 1972 s 9(1): see PARA 303 ante.

4 *Ie* under *ibid* s 9(5): see PARA 306 ante.

5 *Ibid* s 9(8)(a). The reference in the text is a reference to an inspector's powers under s 9 (as amended): see PARAS 304, 307 ante.

6 *Ibid* s 9(8)(b). The reference in the text is a reference to the taking of samples under s 9 (as amended): see PARAS 304, 307 ante.

7 *Ibid* s 9(8)(c). The reference in the text is a reference to information required to be given under s 9 (as amended): see PARAS 304, 307 ante.

8 *Ibid* s 9(8) (amended by virtue of the Criminal Justice Act 1982 s 46). Such a person is liable on summary conviction to a fine not exceeding level 2 on the standard scale: see the Poisons Act 1972 s 9(8) (as so amended). As to the standard scale see PARA 6 note 22 ante.

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(3) ENFORCEMENT, PENALTIES AND PROCEEDINGS/(ii) Penalties and Proceedings/309. Penalties.

(ii) Penalties and Proceedings

309. Penalties.

A person¹ who acts in contravention of or fails to comply² with any of the provisions of the Poisons Act 1972³ or with the Poisons Rules 1982⁴ is liable to a fine in respect of each offence⁵ and, in the case of a continuing offence, he is liable to a further fine⁶ for every day subsequent to the day on which he is convicted of the offence during which the contravention or default continues⁷.

1 For the meaning of 'person' see PARA 21 note 7 ante.

2 The words 'fails to comply' mean a failure to comply with some substantive provision of the Act and do not apply to something which is a requirement if exemption is to be obtained: *R v Staincross Justices, ex p Teasdale* [1961] 1 QB 170, [1960] 3 All ER 572, QBD (a case decided in respect of the Pharmacy and Poisons Act 1933).

3 I.e. the provisions of the Poisons Act 1972 ss 1-7, other than s 6(4) (which provides its own penalty: see PARA 292 ante): s 8(1).

4 I.e. the Poisons Rules 1982, SI 1982/218 (as amended).

5 The penalty on summary conviction is a fine in respect of each offence not exceeding level 4 on the standard scale: Poisons Act 1972 s 8(1) (amended by virtue of the Criminal Justice Act 1982 s 46). As to the standard scale see PARA 6 note 22 ante. As to the time limit for commencing proceedings see PARA 311 post.

6 I.e. not exceeding £10: see the Poisons Act 1972 s 8(1) (as amended: see note 5 supra).

7 Ibid s 8(1) (as amended: see note 5 supra).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(3) ENFORCEMENT, PENALTIES AND PROCEEDINGS/(ii) Penalties and Proceedings/310. Proceedings for default of employees.

310. Proceedings for default of employees.

In the case of proceedings¹ against a person² for or in connection with the sale, exposure for sale or supply of a non-medicinal poison³ effected by an employee, it is not a defence that the employee acted without the authority of the employer⁴, and any material fact known to the employee is deemed to have been known to the employer⁵.

1 le under the Poisons Act 1972 s 8 (as amended): see PARA 309 ante.

2 For the meaning of 'person' see PARA 21 note 7 ante.

3 For the meaning of 'non-medicinal poison' see PARA 287 note 2 ante.

4 Poisons Act 1972 s 8(2)(a).

5 Ibid s 8(2)(b).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(3) ENFORCEMENT, PENALTIES AND PROCEEDINGS/(ii) Penalties and Proceedings/311. Time limit for prosecutions.

311. Time limit for prosecutions.

Notwithstanding any provision in any Act prescribing the period within which summary proceedings may be commenced¹, proceedings for an offence under the Poisons Act 1972 may be commenced at any time within the period of 12 months² after the date of the commission of the offence or, in the case of proceedings instituted by, or by the direction of, the Secretary of State³, either within that period or within the period of three months after the date on which evidence sufficient in his opinion to justify a prosecution for the offence comes to his knowledge⁴, whichever period ends on the later date⁵.

1 See eg the Magistrates' Courts Act 1980 s 127(1); and MAGISTRATES vol 29(2) (Reissue) PARA 589.

2 For the meaning of 'month' see PARA 22 note 15 ante.

3 As to the Secretary of State see PARA 3 note 3 ante. See also PARA 285 note 1 ante.

4 For this purpose, a certificate purporting to be signed by the Secretary of State as to the date on which such evidence came to his knowledge is conclusive evidence of that date: Poisons Act 1972 s 8(3).

5 Ibid s 8(3).

Halsbury's Laws of England/MEDICINAL PRODUCTS AND DRUGS (VOLUME 30(2) (REISSUE))/4. POISONS/(3) ENFORCEMENT, PENALTIES AND PROCEEDINGS/(ii) Penalties and Proceedings/312-400. Analysts' certificates as evidence.

312-400. Analysts' certificates as evidence.

A document purporting to be a certificate signed by a public analyst¹ or a person appointed by the Secretary of State² to make analyses for the purposes of the Poisons Act 1972³, stating the result of an analysis made by him, is admissible in any proceedings under the Act as evidence of the matters stated in it, but either party may require the person by whom the analysis was made to be called as a witness⁴.

1 Poisons Act 1972 s 8(4)(a) (amended by the Food Safety Act 1990 s 59(1), Sch 3 para 16). A public analyst is a public analyst appointed under the Food Safety Act 1990 s 27 (see FOOD vol 18(2) (Reissue) PARA 268): Poisons Act 1972 s 8(4)(a).

2 As to the Secretary of State see PARA 3 note 3 ante. See also PARA 285 note 1 ante.

3 Poisons Act 1972 s 8(4)(b).

4 Ibid s 8(4).